



TEST MENU

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EP-CAM (MOC 31) Myf-4 ER MyoD1 **ERG** Myogenin Factor 13a Myoglobin Factor VIII (Von Willebrand Factor [VWF]) Myosin Smooth Muscle Specific Fascin Naspln A NKX3.1 **FEULGEN** Fite NSE Galectin-3 OCT (2) Gastrin OCT (3/4) GATA-3 P16 GCDFP 15 P40 GFAP P504S (AMACR) GLUT-1 P53 **GLYPCIAN3** P63 Glycophorin A P120 (CATENIN) GMS PAS Gram (-/+) PAS + Distase (PAS-D) Hepatocyte Specific Antigen (Hep-Par1) PAS w/ Fungus **HBME** PAX2 HCG PAX5 HER2- NEU (CERB-2 ONCO PROTEIN) PAX8 HGH PCK (AE1/AE3) (Multicytokeratin-MCK) HHV8 PDL1 (22C3) H. Pylori PDL1 (28-8) HPV (IHC) PDL1 (73-10) **HPV ISH Comprehensive** PDL1 (E1L3NR) HP V ISH Low (6,11) PIN-4 (Prostate Triple Stain) HPV ISH High (16,18) PLAP HPV ISH High Risk (31,33,51) PMS2 HMB45 (Melanoma Marker) PR HNF-1 Beta Prolactin HSV I Prostein HSV II PSA (Prostate Specific Antigen) hTERT PSAP (Prostate Specific Alkaline Antigen Phosphatas) Inhibin A PTEN KAPPA PTH KDX1 Renal Cell Carcinoma (RCC) KI67 Reticulin LAMBDA S100 MAMMAGLOBIN SALL4 MELAN-A Smooth Muscle Actin (SMA) MITF (Microphthalmia Transcription Factor) SMMHC (Myosin SM) MLH1 SOX 10 MSH2 SYNAPTOPHYSIN MSH6 Terminal Deoxy Neucleo Tidyal (TDT) Muc 2 Thrombomodulin MUM 1 Thyroglobulin MURAMIDASE (lysozyme) Treponema Pallidum (spirochete) Muscle Specific Actin TRICHROME (blue)

TRICHROME (green)

Myeloperoxidas

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TTF-1 **TYROSINASE** TRYPTASE (Mast Cell Tryptase – MCT) UROPLAKIN II Villin VIMENTIN VWF WTF1 (Wilm's Tumor) ZAP70 **Molecular Diagnostics** Human Papilloma Virus (HPV) ISH DNA Testing HPV ISH Low (6,11) HPV ISH High (16/18) HPV ISH High (31,33,51) **Infectious Molecular Diagnostics** COVID-19 (Nasal) COVID-19 (Saliva) COVID-19 (Nasal), Flu A, Flu B Flu A, Flu B GI Pathogen (BioFire®) Nail Fungal RSV, Flu A, Flu B UTI **Wound Panel** SPECIAL STAINS AFB ALCIAN BLUE COLLOIDAL IRON **CONGO RED CRYSTAL VIOLET** ELASTIC FITE **GIEMSA** GMS GRAM IRON MELANIN MGP Microorganisms (AFB, GMS) MUCICARMINE PAS **PSA TESTING** SPIROCHETE Stone Analysis

FLUID AND BRUSHING CYTOLOGY

TEST INFORMATION

ALIAS Bladder Washing, Urinary, Instrumented Urine

LABORATORY Cytology
CPT* #88112

TEST DESCRIPTION Detection of suspected malignancy utilizing lavage specimens obtained cystoscopically (bladder washing,

ureteral washing, urethral washing); staging of urologic malignancies.

METHODOLOGY Cytoscopy

TURNAROUND TIME 24 – 72 hours from receipt

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Washing

COLLECTION CONTAINER Preferred: Cytology fixative, specimen container

VOLUME 10 mL (or more) of an appropriately collected cystoscopically derived specimen.

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTIONUnlabeled specimens, Acellular specimens, Specimens with excessive lubricant, Specimens in incorrect fixative (such as formalin) can only be processed as a cell block.

STORAGE AND TRANSPORT

REQUIRED INFORMATION Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number),

and where appropriate, specimen source.

STORAGE AND TRANSPORT Fresh Specimen Unfixed specimens remain stable for 2 hours at room temperature. Specimens fixed in cytology

fixative are stable for 24 hours. Refrigerated unfixed specimens which are not transported within 2 hours must

be refrigerated and can remain stable for 3 days. Do not freeze the specimen.

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.

Standard pickup hours are 7am to 7pm ET (Monday to Friday)

Please contact us with any questions, shipping label inquiries, and any special arrangements needed. Send via FedEx or UPS to: Acupath Laboratories, Inc.

28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

FINE NEEDLE ASPIRATE (FNA) CYTOLOGY

TEST INFORMATION

ALIAS FNA – Breast, Breast Cyst Fluids, Lymph Nodes, Salivary Gland, Thyroid, Thyroid Cysts

LABORATORY Cytology
CPT* 88173, 88305

TEST DESCRIPTION Diagnose primary or metastatic malignant neoplasms; differential diagnosis of benign versus malignant

processes.

METHODOLOGY The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining

material. Filters, thin preps, and/or cytospins will be made along with a cell block, if applicable. Microscopic

examination is performed.

TURNAROUND TIME 24 – 72 hours upon receipt

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Fine Needle Aspirated material

COLLECTION CONTAINER Preferred - Slide(s), Block(s), Coplin jar(s)

Other acceptable

Do not discard the needle yet. Rinse the needle in a labeled container of balanced salt solution and an equal volume of 50% ethanol. Send all material to the lab.

Alternative to making direct smears (less desirable, but acceptable): Express the specimen directly into a

balanced salt solution and an equal volume of either 50% ethyl alcohol or Saccomanno fixative. Send to the

laboratory for slide preparation.

VOLUME Express one to two drops of material in the hub, stop, release negative pressure on the syringe, and pull out to

make the slides. (If too much material is expressed, the slides will be too thick for optimal interpretation. A thin

monolayer of cells is desired.

SPECIAL INSTRUCTIONS Include patient's name, date of birth, Social Security number, source, previous malignancy, drug therapy,

radiation therapy, and all other pertinent clinical information on the test request form.

It is recommended to do an aspirate only on a palpable mass. ("Blind" sticks are discouraged except for those under radiologic guidance.) A **minimum** of two separate passes should be done, preferably more (inadequate specimens result in false-negative diagnosis).

It is very important to specify the source of the specimen along with clinical history and clinical impression. If a cyst is aspirated, indicate this fact on the test request form; it will most likely be hypocellular but will not be a false-negative. If the patient has a known diagnosis of malignancy, please include that information on the test request form. Whatever the specimen source, please include your clinical impression and reason for doing the aspiration (e.g., "fine-needle aspiration on lymph node: suspect lymphoma vs metastatic carcinoma vs infectious process").

If an infectious process is in the differential, please submit a portion of the specimen to microbiology in an appropriate sterile medium or transport container. Once the specimen is smeared and/or put in an alcohol container, it is unsuitable for culture.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Improper labeling; improper fixation; air-drying artifact; blood in sample; or specimen submitted in vial that expired according to manufacturer's label.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Use a small gauge (eg, 25-g or 22-g) needle to avoid dilution with blood. Immobilize the palpable mass with your nondominant hand. Using a syringe holder will allow you to keep your nondominant hand on the mass. Insert the needle into the mass and pull back on the syringe plunger, creating negative pressure, using it as a cutting tool. Make short 5 mm "in-and-out" motions until you see material coming into the hub of the needle. When you start to see material in the hub, stop, release negative pressure on the syringe, and pull out to make the slides. Do not aspirate material into the syringe or dilute with blood or saline. This interferes with making good direct smears. (See preparation of slides below.) If you do not see any material at all in the hub or syringe, continue the short 5 mm strokes until you have done 15 to 20 strokes. Pull out and attempt to express material on slides (see below). Repeat the above procedure again using a clean needle for a second pass (and more passes if needed). Many physicians use no local anesthesia. If you decide to give a local, please avoid aspirating the local anesthetic into the needle. It will dilute as well as distort the specimen.

Making direct smears (preferred method):

Use a graphite pencil or print labels for 8 to 10 slides with the patient's name before starting the procedure.

- After aspiration, make sure to have positive pressure in the syringe (if need be, remove the needle, pull back the plunger, then reattach the needle to gain positive pressure). Avoid aspirating the material from the needle into the syringe.
- Touch the end of the needle to the end of the glass slide and express one to two drops of material. (If too much material is expressed, the slides will be too thick for optimal interpretation. A thin monolayer of cells is desired.)
- Place a second slide on top of the first, allowing the drop to spread, then gently pull slides apart toward opposite end. Fix immediately in 95% ethyl alcohol. Note: It is imperative to fix the slides immediately to avoid air drying. Continue making more slides in this fashion until all the material in the needle is used.
- Do not discard the needle yet. Rinse the needle in a labeled container of balanced salt solution and an equal volume of 50% ethanol. Send all material to the lab.
- Alternative to making direct smears (less desirable, but acceptable): Express the specimen directly into a balanced salt solution and an equal volume of either 50% ethyl alcohol or Saccomanno fixative. Send to the laboratory for slide preparation.
- If a cyst is aspirated, use the alternative method outlined above. The laboratory will spin the specimen for concentration.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen: Maintain the specimen in cytology fixative at room temperature.

Block or Slides:

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements needed.

- Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
 Standard pickup hours are 7am to 7pm ET (Monday to Friday)
- Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

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URINE CYTOLOGY

TEST INFORMATION

ALIAS Urine, Bladder Washings/Lavage

LABORATORY Cytology
CPT* #88112

TEST DESCRIPTION Used to detect abnormal cells in urine specimens.

METHODOLOGY The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining

material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic

examination is performed.

TURNAROUND TIME 2 – 6 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ **TC**, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE
• Urine, voided

Urine, catheterizedBladder washUreteral washPelvic wash

COLLECTION CONTAINER Preferred

ThinPrep® PreservCyt Composition/ingredient information: 35-55% Methanol

Other acceptable

ThinPrep® CytoLyt Composition/ingredient information: 20-50% Methanol, 40-70% Water Carbowax™ Composition/ingredient information: 2% polyethylene glycol in 50% ethanol

30-60% Methanol Composition/ingredient information: 30-60% Methanol

PreserveCell Solution Composition/ingredient information: TBD

VOLUME 66 ml of voided urine mixed with 33 ml of preservative.

SPECIAL INSTRUCTIONS Urine refrigerated with preservative has been shown to be stable for 1 week. After 1 week, while collection of a

new voided urine is best, this is not an exclusion criteria.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure - Patient Preparation

- Step 1. Void and discard the first morning urine.
- Step 2. Females, clean the genital area with a cloth wiping from the front to the back. Avoid the anal area.
- Step 3. Wash hands with soap and water.
- Step 4. Open the sterile urine container.
- Step 5. Start urinating in the toilet then stop.
- Step 6. Urinate into the container. Fill approximately ¾ full with voided urine.
- Step 7. Finish urinating if needed.

Note: If unable to urinate, patient should hydrate, sit for an hour, then reattempt.

Collection Procedure - Office

- Step 1. Use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Perform urine collection in a sterile container.
- Step 3. If urine collected exceeds 66ml, pour off excess in a second specimen collection cup.

 Transfer the voided urine from the sterile container to the ThinPrep PreservCyt container, so that they are mixed in a 2:1 (v:v) ratio, two parts urine, one part fixative. Do not exceed the 90 ml line.
- Step 4. Submit multiple containers when greater than 60 ml of urine is voided by the patient.

 Additional urine is recommended when also requesting
- Step 5. Ensure the cap is tightly sealed to prevent leakage.

 Place container into a biohazard bag and completed requisition in the side pocket of the bag.

 Send specimens to the laboratory as soon as possible after collection.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

• Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.

If not ordering electronically: complete and send the Acupath Uropathology Test Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

All primary specimen containers must be labeled with at least two patient-specific identifiers. A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. Examples of acceptable identifiers include, but are not limited to: patient name, date of birth, hospital number, requisition number, accession number.

STORAGE AND TRANSPORT

Fresh Specimen: Specimen is stable at room temperature with fixative for 24 hours or can be refrigerated for up to 3 days

SPECIMEN PICK-UP OR SHIPPING

Standard pickup hours are 7am to 7pm ET (Monday to Friday)

• Send via FedEx or UPS to:

Please contact us with any questions, shipping label inquiries, and any special arrangements needed.

Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

Direct Immunofluorescence (DIF)

TEST INFORMATION

ALIAS DIF

LABORATORY Laboratory
CPT* 88346, 88350

TEST DESCRIPTION Direct Immunofluorescence (DIF) testing is the application of fluoresceinated antibodies to a frozen section of

skin. The DIF test determines the deposition of immunoreactants in a patient's tissue and is useful in the

diagnosis of suspected autoimmune disease, connective tissue diseases and vasculitis.

METHODOLOGY Direct Immunofluorescence

TURNAROUND TIME 3-7 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Tissue: skin, mucosa (oral, conjunctival, genital, esophageal), other epithelium (gastrointestinal, respiratory,

urinary).

COLLECTION CONTAINER

VOLUME

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Test Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Room temperature. Also acceptable: Refrigerated.

SPECIMEN PICK-UP OR SHIPPING

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 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

Leukemia/Lymphoma Immunophenotyping Panel

TEST INFORMATION

ALIAS L/L, Flow, Leukemia, Lymphoma

LABORATORY Flow Cytometry

CPT* 88184, 88185, 88187, 88188, 88189, 85060, 88108, 88173

TEST DESCRIPTION This test is used to diagnose and monitor hematopoietic neoplasms. Anemia, thrombocytosis, lymphocytosis,

impaired bone marrow function, and lymphadenopathy are typical clinical indications for testing.

Markers analyzed in peripheral blood and bone marrow specimens include: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD25, CD33, CD34, CD36, CD38, CD45, CD56, CD57, CD64, CD103, CD117, FMC7, HLA-DR, kappa, lambda. Markers analyzed in tissue biopsy specimens include: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD16, CD19, CD20, CD22, CD23, CD25, CD38, CD45, CD56, CD57, CD103, FMC7, kappa, lambda. The number of markers performed may change depending on the

pathologist's interpretation and the specimen cellularity.

METHODOLOGY Immunophenotyping by Flow Cytometry

TURNAROUND TIME 1 - 3 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Peripheral Blood

Bone Marrow Aspirate

Fresh lymphoid tissue specimen: biopsies or fine needle aspirate (FNA)

Cerebral spinal fluid (CSF)

COLLECTION CONTAINER Peripheral Blood & Bone Marrow

Sodium Heparin or green top tube (*preferred*) EDTA or lavender top tube (*acceptable*)

Fresh Tissue: Biopsies or FNAs of extra nodal tissue, fresh lymph node, spleen

Submit in a sterile container with RPMI. Tissue should be completely immersed in RPMI. RPMI should be red-orange in color. Do not use RPMI if it is cloudy, yellow, or expired.

 $Note: For \ histological \ correlation, \ it \ is \ suggested \ but \ not \ essential \ to \ submit \ a \ separate \ additional \ portion \ of \ the$

tissue biopsy in 10% neutral buffered formalin.

Cerebral Spinal Fluid

Submit in a sterile container without any preservative or fixative.

VOLUME Peripheral Blood

3 - 5 ml preferred; minimum 1 ml

(Note: Minimum does not allow for ancillary testing.)

Bone Marrow

1 - 4 ml preferred; minimum 1 ml

(Note: Minimum does not allow for ancillary testing.)

Fresh Tissue

Approximately, 0.5 to $1.0\ cm^3$ of fresh tissue. Volume or tissue size is dependent on the leukocyte cellularity.

Cerebral Spinal Fluid

Minimum 1 ml.

(Note: The low cell count of CSF samples, combined with a rapidly declining leukocyte viability, makes CSF

analysis by flow cytometry challenging.)

SPECIAL INSTRUCTIONS Specimens should be received within 48 hrs of collection to ensure sample integrity and cell viability.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- · Test Requisition form completed and signed
- Billing information or payment (include copy of front and back of insurance card)
- . Clinical Indication for testing and prior relevant results
- Specimen source (site, type)
- Date and time of collection
- CBC report with differential, if available. Must accompany bone marrow specimen.

CAUSES FOR REJECTION

Clotted, fixed, frozen or hemolyzed sample; sample viability <50%. Improper labeling. Incorrect preservative; compromised collection tube; or a delay in transport (sample age beyond 72 hrs. at arrival to laboratory).

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

- Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Perform specimen collection following collection protocol.
- Step 3. Ensure the collection container cap is tightly sealed to prevent leakage.
- Step 4. Document collection date and time information.

Request Form

Complete and send the Acupath Hematopathology Test Requestion Form with the specimen.

Specimen Labeling

Specimens must be labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and specimen source.

STORAGE AND TRANSPORT A Transport specimen to the

laboratory immediately after

received within 24 hours of

collection, as testing must be performed within 48 hours to ensure

collection. Specimens should be

sample integrity and cell viability.

Peripheral Blood & Bone Marrow

Store and transport at room temperature (15-25°C or 60-76°F).

Fresh Tissue

Store and transport in RPMI at refrigerated temperature (2-8°C or 36-46°F). Sterile saline may be used if RPMI is unavailable. Best shipped with a cold pack. Ensure cold pack does not come in direct contact with the specimen. Do not freeze.

Cerebral Spinal Fluid

Store and transport at refrigerated temperature (2-8°C or 36-46°F). May be shipped with a cold pack. Ensure cold pack does not come in direct contact with the specimen. Do not freeze.

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements needed.

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- Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803 Attn: Accessioning Department

REFERENCES

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- Van de Loosdrecht AA, Alhan C, et al. Standardization of flow cytometry in myelodysplastic syndromes: report from the first European Leukemia Networking conference on flow cytometry in myelodysplastic syndromes. Haematologica. 2009Aug;94(8):1124-34 PMID: 19546437
- The CPT codes included in this publication are in accordance with Current Procedural Terminology, a publication of the
 American Medical Association. CPT codes are provided here for the convenience of our clients; however, correct coding
 often varies from one carrier to another, and Acupath may bill specific carriers using codes other than those shown. Clients
 who bill for services should verify the code(s) with the applicable payer to confirm that their use is appropriate in each case.

Barrett's FISH Panel

TEST INFORMATION

ALIAS FISH, MYC, P16, CDKN2A, ERBB2/HER2, ZNF217, Barrett's Esophagus, Esophageal Adenocarcinoma

LABORATORY FISH CPT* 88377

TEST DESCRIPTION The Barrett's Esophagus FISH panel is a tool for detecting chromosomal abnormalities known to be associated

with Barrett's Esophagus. Patients with Barrett's Esophagus (BE) are at an increased risk for progression to esophageal cancer. Results are intended for use as an adjunct to existing clinical and pathologic information.

METHODOLOGY Fluorescence in situ Hybridization

TURNAROUND TIME 2 - 5 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Esophageal brushing COLLECTION CONTAINER PREFERRED

Preservative Name Composition/ingredient information

ThinPrep® PreservCyt 35-55% Methanol

OTHER ACCEPTABLE

<u>Preservative Name</u> <u>Composition/ingredient information</u>

30-60% Methanol 30-60% Methanol

VOLUME ThinPrep PreservCyt container with ≥ 17 ml of preservative and clipped brush inside.

SPECIAL INSTRUCTIONS Esophageal brushings refrigerated with preservative has been shown to be stable for 1 week; however, it is

recommended that specimens be processed within 72 hours of collection.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

CAUSES FOR REJECTION

Electronic Order or completed Acupath Test Requisition form with prior relevant results.

NCLUDED WITH EACH SAMPLE

• Billing information or payment (include copy of front and back of insurance card).

Improper labeling; incorrect preservative/fixative; delay in transport; insufficient tissue/inadequate specimen

cellularity; collection date/time not provided.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.

Step 2. Perform specimen collection following endoscopy and surgical protocol.

Step 3. Nodular areas are brushed first, if present.

Step 4. Next, perform a pan brushing (using a separate brush) of the esophageal mucosa.

Step 5. Immediately after collection, place each brush into a separate vial of PreservCyt fixative that is labeled with two unique patient identifiers, and area brushed (nodular or pan).

Step 6. Free cells from brush into PreservCyt as quickly as possible by rotating the brush in the solution 10 times and then swirling the brush vigorously.

Step 7. Snip off the brush in the PreservCyt solution and tighten the cap.

Step 8. Ensure the collection container cap is tightly sealed to prevent leakage.

Step 9. Document collection date and time on requisition.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath GI Requisition with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Store and transport at room temperature. Refrigeration acceptable but not required. Do not freeze. Forward specimen to the laboratory immediately after collection.

Block or Slides

Store and transport at room temperature.

SPECIMEN PICK-UP OR SHIPPING

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 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803 Attn: Accessioning Department

REFERENCES

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Bladder Cancer FISH Panel

TEST INFORMATION

ALIAS FISH, UroVysion®, Urothelial Carcinoma FISH, Bladder Cancer Recurrence

LABORATORY FISH

CPT* 88121, automated 88120, manual

88112, cell enrichment

TEST DESCRIPTION The UroVysion Bladder Cancer Kit (UroVysion Kit) is designed to detect aneuploidy for chromosomes 3, 7, 17,

and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with

hematuria suspected of having bladder cancer.

METHODOLOGY Fluorescence in situ Hybridization

TURNAROUND TIME 2 - 5 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE

✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Voided urine

Bladder washing

COLLECTION CONTAINER Preferred

ThinPrep® PreservCyt Composition/ingredient information: 35-55% Methanol

Other acceptable

ThinPrep® CytoLyt Composition/ingredient information: 20-50% Methanol, 40-70% Water Carbowax™ Composition/ingredient information: 2% polyethylene glycol in 50% ethanol

30-60% Methanol Composition/ingredient information: 30-60% Methanol

PreserveCell Solution Composition/ingredient information: TBD

VOLUME 66 ml of voided urine mixed with 33 ml of preservative.

SPECIAL INSTRUCTIONS Urine refrigerated with preservative has been shown to be stable for 1 week; however, it is recommended that

specimens be processed within 72 hours of collection.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Improper labeling; incorrect preservative/fixative; delay in transport; insufficient tissue/inadequate specimen cellularity; collection date/time not provided.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.

Step 2. Perform urine collection in a sterile container.

Step 3. If urine collected exceeds 66ml, pour off excess in a second specimen collection cup.

Transfer the voided urine from the sterile container to the ThinPrep PreservCyt container, so that they are mixed in a 2:1 (v:v) ratio, two parts urine, one part fixative. Do not exceed the 90 ml line.

Step 4. Ensure the cap is tightly sealed to prevent leakage.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Uropathology Test Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Store and transport at room temperature. Refrigeration acceptable but not required. Do not freeze. Forward specimen to the laboratory immediately after collection.

Block or Slides

Store and transport at room temperature.

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements needed.

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup. Standard pickup hours are 7am to 7pm ET (Monday to Friday)

 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803 Attn: Accessioning Department

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Dermatologic FISH Panel

TEST INFORMATION

ALIAS FISH, Melanoma FISH Panel, Spitz FISH Panel, RREB1, MYB, CCND1, CEP6, HRAS

LABORATORY FISH CPT* 88377

TEST DESCRIPTION MELANOMA FISH PANEL

The Melanoma FISH panel is designed to detect genetic abnormalities in formalin-fixed paraffin-embedded tissue specimens, which have been shown to be absent in benign melanocytic nevi but present in malignant melanomas. Results are intended for use as an adjunct to existing clinic al and pathologic information.

Probes: RREB1, MYB, CEP6, CCND1

SPITZ NEVUS FISH PANEL

The Spitz Nevus FISH Panel is designed to confirm a Spitz Nevus diagnosis in a subset of patients whose tissues exhibit both malignant melanoma and Spitz Nevus features. Results are intended for use as an adjunct to existing clinic all and pathologic information.

Probes: HRAS, CCND1

METHODOLOGY Fluorescence in situ Hybridization

TURNAROUND TIME 2 - 14 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ **TC**, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded (FFPE) tissue

COLLECTION CONTAINER 10% neutral buffered formalin

VOLUME OPTION 1: SUBMIT BLOCK

FFPE tissue block

• One H&E slide, with a clearly marked area of interest (required)

Pathology Report

OPTION 2: SUBMIT SLIDES

• Five unstained 4-micron positively charged slides (minimum of two slides needed per panel)

One H&E slide, with a clearly marked area of interest (required)

Pathology Report

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Improper labeling; incorrect preservative/fixative; delay in transport; insufficient tissue/inadequate specimen cellularity; collection date/time not provided.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.

Step 2. Perform specimen collection following surgical protocol.

Step 3. Ensure the collection container cap is tightly sealed to prevent leakage.

Step 4. Document collection date and time on requisition.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Dermatopathology Test Requisition with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Store and transport at room temperature. Refrigeration acceptable but not required. Do not freeze. Forward specimen to the laboratory immediately after collection.

Block or Slides

Store and transport at room temperature.

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements

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Attn: Accessioning Department

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PathVysion®

TEST INFORMATION

ALIAS FISH, HER2, HER2/neu, ERBB2, c-erbB2

LABORATORY FISH CPT* 88377

TEST DESCRIPTION The PathVysion HER-2 DNA Probe Kit (PathVysion Kit) is designed to detect amplification of the HER-2/neu

gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. The kit contains a DNA probe specific for the HER-2/neu gene locus (17q11.2-q12), which fluoresces in orange, and a DNA probe specific for the alpha satellite DNA sequence at the centromeric region

of chromosome 17 (17p11.1-q11.1), which fluoresces in green.

METHODOLOGY Fluorescence in situ Hybridization

TURNAROUND TIME 2 - 7 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE

Formalin-fixed, paraffin-embedded (FFPE) tissue from invasive primary or metastatic breast or gastric cancer.

COLLECTION CONTAINER

* An IHC score is required for

complete FISH interpretation.

If IHC is not available, or has not been performed, Acupath can

perform this service with a separate

10% neutral buffered formalin

VOLUME

billing fee.

OPTION 1: SUBMIT BLOCK

- FFPE tissue block
- One H&E slide, with a clearly marked area of interest
- Pathology Report, including IHC score*

OPTION 2: SUBMIT SLIDES

- Five unstained 4-micron positively charged slides (minimum of two slides needed)

 Note: If slides are being submitted for testing, please document on the requisition the date of when slides were cut. Ideally, sections should not be used for HER2 testing if cut >6 weeks earlier. It is at the Medical Director's discretion to report out such results.
- · One H&E slide, with a clearly marked area of interest
- Pathology Report, including IHC score*

SPECIAL INSTRUCTIONS

As per CAP-ASCO guidelines, specimens should be fixed in 10% neutral buffered formalin for no less than 6 hours and no more than 72 hours. The volume of formalin should be at least 10 times the volume of the specimen.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).
- Pathology report must include ASCO/CAP required elements, including:
 - Immunohistochemistry (IHC) result
 - Collection date
 - Collection time
 - Time tissue was placed in fixative, if different than collection time
 - Cold ischemic time
 - Note: time from tissue removal to initiation of fixation should be less than or equal to one hour
 - Specimen source (site, type)
 - Type of fixative used
 - Total fixation time (if specimen was processed elsewhere)

CAUSES FOR REJECTION

Improper labeling; incorrect preservative/fixative; delay in transport; insufficient tissue/inadequate specimen cellularity; collection date/time not provided; decalcified specimens.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

- Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Perform specimen collection following surgical protocol.
- Step 3. Ensure the collection container cap is tightly sealed to prevent leakage.
- Step 4. Document collection date, time, and fixation information.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Plastic Surgery Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Store and transport at room temperature. Refrigeration acceptable but not required. Do not freeze. Forward specimen to the laboratory immediately after collection.

Block or Slides

Store and transport at room temperature.

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements needed. Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
 Standard pickup hours are 7am to 7pm ET (Monday to Friday)

 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

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Prostate FISH Panel

TEST INFORMATION

ALIAS FISH, PTEN, TMPRSS2/ERG, ERG, 10q23.31, 21q22, 21q22 del-TECT

LABORATORY FISH
CPT* 88377

TEST DESCRIPTION PTEN FISH PANEL

The PTEN FISH Panel is designed to detect deletions of the PTEN gene. It consists of the PTEN probe (labeled in orange), WAPAL/BMPR1A probe (labeled in green), FAS probe (labeled in aqua), and centromere 10 probe (labeled in red). The combination of the three additional colored probes (green, orange and aqua) in close proximity assists in eliminating the possibility of truncation of this region, and also in determining the actual size of the deletion. The centromere probe is included to help determine if chromosome 10 monosomies or polysomies are present.

TMPRSS2/ERG FISH PANEL

The TMPRSS2/ERG FISH Panel is designed to detect alterations of the chromosome 21q22.2 region, and, specifically, an ERG:TMPRSS2 fusion. Four probes are included: probe A (labeled in red) is located slightly centromeric to the ERG gene. Probe B (labeled in orange) is located slightly telomeric to the ERG gene and spans the HMGN1 gene. Probe C (labeled in aqua) covers most of the DSCAM gene. Probe D (labeled in green) is located telomeric to the TMPRSS2 gene. The combination of the four adjacent probes labeled in different colors (red, orange, aqua, green) assists in deciphering alterations of the 21q22.2 region, particularly when examining tumor tissue sections.

METHODOLOGY Fluorescence in situ Hybridization

TURNAROUND TIME 2 - 10 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

√ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded (FFPE) tissue

COLLECTION CONTAINER 10% neutral buffered formalin

VOLUME OPTION 1: SUBMIT BLOCK

FFPE tissue block

One H&E slide, with a clearly marked area of interest (required)

Pathology Report

OPTION 2: SUBMIT SLIDES

• Six unstained 4-micron positively charged slides (minimum of four slides needed)

One H&E slide, with a clearly marked area of interest (required)

Pathology Report

SPECIAL INSTRUCTIONS None

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

Pathology report with IHC results, if available

CAUSES FOR REJECTION Improper labeling; incorrect preservative/fixative; delay in transport; insufficient tissue/inadequate specimen cellularity; collection date/time not provided.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

- Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Perform specimen collection following surgical protocol.
- Step 3. Place specimen in prefilled 10% neutral buffered formalin container.
- Step 4. Ensure the collection container cap is tightly sealed to prevent leakage.
- Step 5. Ensure the collection container is Labeled with two forms of patient identification (i.e. name and DOB).
- Step 6. Document collection date and time on requisition.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Uropathology Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Store and transport at room temperature. Refrigeration acceptable but not required. Do not freeze. Forward specimen to the laboratory immediately after collection.

Block or Slides

Store and transport at room temperature.

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements needed. Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
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Attn: Accessioning Department

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TERC FISH Panel

TEST INFORMATION

ALIAS FISH, TERC, Con3_vB

LABORATORY FISH CPT* 88377

TEST DESCRIPTION The TERC FISH panel is a tool for detecting chromosomal abnormalities known to be associated with high grade

HPV. Results are intended for use as an adjunct to existing clinical and pathologic information.

METHODOLOGY Fluorescence in situ Hybridization

TURNAROUND TIME 2 - 10 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Anal

CervicalOral

COLLECTION CONTAINER FOR SPECIMEN TYPES: ANAL, CERVICAL, ORAL

<u>Preservative Name</u> <u>Composition/ingredient information</u>

ThinPrep® PreservCyt 35-55% Methanol 30-60% Methanol 30-60% Methanol 30-60% Methanol

VOLUME ANAL

Cytological swab immersed in 20ml ThinPrep® PreservCyt

CERVICAL

Endocervical cytology specimen immersed in 20ml ThinPrep® PreservCyt

PAP brush immersed in 20ml ThinPrep® PreservCyt

ORAL

10ml of Listerine mouthwash and mouth swab immersed in 20 ml ThinPrep® PreservCyt

SPECIAL INSTRUCTIONS Cytological samples refrigerated with preservative have been shown to be stable for 1 week; however, it is

recommended that specimens be processed within 72 hours of collection.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION Improper labeling; incorrect preservative/fixative; delay in transport; insufficient tissue/inadequate specimen

cellularity; collection date/time not provided.

COLLECTION AND TRANSPORT

Collection Procedure: Anal Specimens

- Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Use cytological swab to collect cells in the area of interest.
- Step 3. Immediately after collection, immerse swab into the vial of PreservCyt that is labeled with two unique patient identifiers. It should have at least 20ml of fixative inside.
- Step 4. Free cells from swab into the preservative by swirling the swab in the solution.
- Step 5. Leave the swab inside the container. Snip off the end if necessary to make it fit.
- Step 6. Ensure the collection container cap is tightly sealed to prevent leakage.
- Step 7. Document collection date and time on requisition.

Collection Procedure: Cervical Specimens

- Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Use cytological swab or a PAP brush to collect cells in the area of interest.
- Step 3. Immediately after collection, immerse swab/brush into the vial of PreservCyt that is labeled with two unique patient identifiers. It should have at least 20ml of fixative inside.
- Step 4. Free cells from swab or brush into the preservative by swirling the swab/brush in the solution.
- Step 5. Leave the swab or brush inside the container. Snip off the end if necessary to make it fit.
- Step 6. Ensure the collection container cap is tightly sealed to prevent leakage.
- Step 7. Document collection date and time on requisition.

Collection Procedure: Oral Specimens

- Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.
- Step 2. Rinse mouth for 5~10 seconds with 10ml of Listerine mouthwash.
- Step 3. Transfer the mouthwash into a ThinPrep container (it should have at least 20 ml of PreservCyt fixative inside).
- Step 4. Locate a swab and use it to gently rub the inside of the cheek, to collect cells.
- Step 5. Immediately after collection, immerse swab into the vial of PreservCyt that is labeled with two unique patient identifiers.
- Step 6. Leave the swab or brush inside the container. Snip off the end if necessary to make it fit.
- Step 7. Ensure the collection container cap is tightly sealed to prevent leakage.
- Step 8. Document collection date and time on requisition.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Colon & Rectal Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Store and transport at room temperature. Refrigeration acceptable but not required. Do not freeze. Forward specimen to the laboratory immediately after collection.

Block or Slides

Store and transport at room temperature.

SPECIMEN PICK-UP OR SHIPPING

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Acupath Laboratories, Inc.

28 S. Terminal Drive

Plainview, NY 11803

Attn: Accessioning Department

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GENERAL HISTOLOGY/MORPHOLOGY

TEST INFORMATION

ALIAS

LABORATORY

CPT*

TEST DESCRIPTION

Need Info

Breast Pathology, Dermatopathology, ENT Pathology, Family Practice Pathology, Gastrointestinal Pathology, General Pathology, Gynecologic Pathology, Hematopathology, Ophthalmic Pathology, Oral Maxillofacial Pathology, Orthopedic Pathology, Plastic Surgery Pathology, Podiatric Pathology, Pulmonary Pathology,

Uropathology

METHODOLOGY

TURNAROUND TIME

24 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE

✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE

COLLECTION CONTAINER

VOLUME

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath General Surgery Pathology

Tissue Processing Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
 Standard pickup hours are 7am to 7pm ET (Monday to Friday)

Please contact us with any questions, shipping label inquiries, and any special arrangements needed. Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

hTERT Icc

TEST INFORMATION

ALIAS Human Telomerase Reverse Transcriptase

LABORATORY Pathology

CPT*

TEST DESCRIPTION Used to detect abnormal cells in urine specimens.

METHODOLOGY The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining

material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic

examination is performed.

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

▼ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Urine, voided

Urine, catheterized Urine, free-catch

COLLECTION CONTAINER Preferred

ThinPrep® PreservCyt Composition/ingredient information: 35-55% Methanol

Other acceptable

ThinPrep® CytoLyt Composition/ingredient information: 20-50% Methanol, 40-70% Water Carbowax™ Composition/ingredient information: 2% polyethylene glycol in 50% ethanol

30-60% Methanol Composition/ingredient information: 30-60% Methanol

PreserveCell Solution Composition/ingredient information: TBD

VOLUME 66 ml of voided urine mixed with 33 ml of preservative.

SPECIAL INSTRUCTIONS Urine refrigerated with preservative has been shown to be stable for 1 week. After 1 week, while collection of a

new voided urine is best, this is not an exclusion criteria.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

Electronic Order or completed Acupath Test Requisition form with prior relevant results.

Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Urine refrigerated with preservative has been shown to be stable for 1 week. After 1 week, while collection of a new voided urine is best, this is not an exclusion criteria. Improper labeling; improper fixation; 24-hour collection; undue delay in transport; specimen submitted in vial that expired according to manufacturer's label; frozen specimen.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. Void and discard the first morning urine.

Step 2. Females, clean the genital area with a cloth wiping from the front to the back. Avoid the anal area.

Step 3. Wash hands with soap and water.

Step 4. Open the sterile urine container.

Step 5. Start urinating in the toilet then stop.

Step 6. Urinate into the container. Fill approximately $\frac{3}{2}$ full with voided urine.

Step 7. Finish urinating if needed.

Note: If unable to urinate, patient should hydrate, sit for an hour, then reattempt.

Collection Procedure - Office

Step 1. Use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.

Step 2. Perform urine collection in a sterile container.

Step 3. If urine collected exceeds 66ml, pour off excess in a second specimen collection cup.

Transfer the voided urine from the sterile container to the ThinPrep PreservCyt container, so that they are mixed in a 2:1 (v:v) ratio, two parts urine, one part fixative. Do not exceed the 90 ml line.

Step 4. Submit multiple containers when greater than 60 ml of urine is voided by the patient. Additional urine is recommended when also requesting

Step 5. Ensure the cap is tightly sealed to prevent leakage.

Place container into a biohazard bag and completed requisition in the side pocket of the bag. Send specimens to the laboratory as soon as possible after collection.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Block or Slides

SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

URO17

TEST INFORMATION

ALIAS URO17 LABORATORY Pathology

CPT*

TEST DESCRIPTION Used to detect abnormal cells in urine specimens.

METHODOLOGY The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining

material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic

examination is performed.

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE • Urine, voided

Urine, catheterized Urine, free-catch

COLLECTION CONTAINER Preferred

ThinPrep® PreservCyt Composition/ingredient information: 35-55% Methanol

Other acceptable

ThinPrep® CytoLyt Composition/ingredient information: 20-50% Methanol, 40-70% Water Carbowax™ Composition/ingredient information: 2% polyethylene glycol in 50% ethanol

30-60% Methanol Composition/ingredient information: 30-60% Methanol

PreserveCell Solution Composition/ingredient information: TBD

VOLUME 66 ml of voided urine mixed with 33 ml of preservative.

SPECIAL INSTRUCTIONS Urine refrigerated with preservative has been shown to be stable for 1 week. After 1 week, while collection of a

new voided urine is best, this is not an exclusion criteria.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

Electronic Order or completed Acupath Test Requisition form with prior relevant results.

CLUDED WITH EACH SAMPLE• **Billing information** or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Urine refrigerated with preservative has been shown to be stable for 1 week. After 1 week, while collection of a new voided urine is best, this is not an exclusion criteria. Improper labeling; improper fixation; 24-hour collection; undue delay in transport; specimen submitted in vial that expired according to manufacturer's label;

frozen specimen.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure – Patient Preparation

Step 1. Void and discard the first morning urine.

Step 2. Females, clean the genital area with a cloth wiping from the front to the back. Avoid the anal area.

Step 3. Wash hands with soap and water.

Step 4. Open the sterile urine container.

Step 5. Start urinating in the toilet then stop.

Step 6. Urinate into the container. Fill approximately ¾ full with voided urine.

Step 7. Finish urinating if needed.

Note: If unable to urinate, patient should hydrate, sit for an hour, then reattempt.

Collection Procedure - Office

Step 1. Use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.

Step 2. Perform urine collection in a sterile container.

Step 3. If urine collected exceeds 66ml, pour off excess in a second specimen collection cup.

Transfer the voided urine from the sterile container to the ThinPrep PreservCyt container, so that they are mixed in a 2:1 (v:v) ratio, two parts urine, one part fixative. Do not exceed the 90 ml line.

Step 4. Submit multiple containers when greater than 60 ml of urine is voided by the patient.

Additional urine is recommended when also requesting

Step 5. Ensure the cap is tightly sealed to prevent leakage.

Place container into a biohazard bag and completed requisition in the side pocket of the bag. Send specimens to the laboratory as soon as possible after collection.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Uropathology Test Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Fresh Specimen

Block or Slides

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any questions, shipping label inquiries, and any special arrangements

Acupa

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
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Attn: Accessioning Department

REFERENCES

REFERENCES

needed.

AFB (-/+)

TEST INFORMATION

ALIAS Acid Fast Bacillus

LABORATORY Pathology

CPT* 88312

TEST DESCRIPTION AFB III Staining Kit is intended for use as a qualitative histologic stain to selectively demonstrate

Mycobacterium and other acid fast organisms or components in formalin fixed, paraffin-embedded tissue. The reagents are applied to tissue on microscope slides and mixed over the entire specimen. The staining reaction is based on the application of pararosaniline in phenol and alcohol, which enhances staining and dissolves the dye, to stain all components in the section. Decolorizer, an acid alcohol reagent, is applied to remove the color from all tissue elements other than the acid fast components. Organisms and components that remain stained

are believed to have selective permeability to the carbol fuchsin.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 - 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ALB PAS IHC STAINS

TEST INFORMATION

ALIAS Alcian Blue PAS
LABORATORY Pathology
CPT* 88313

TEST DESCRIPTIONThe PAS Staining Kit uses Periodic Acid reagent to oxidize glycols to aldehydes. The Schiff's Reagent forms a

colorless dialdehyde compound that is transformed to the magenta staining of glycol containing cellular components. The chemical properties of Alcian Blue enable the dye to detect weakly acidic mucins in goblet

cells. Alcian Blue for PAS, with a pH of 2.5, stains acid mucopolysaccharides blue.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

 $\label{thm:conditional} \textit{Test requests can be ordered electronically through our EMR system}.$

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ALCIAN BLUE

TEST INFORMATION

ALIAS Alcian Blue
LABORATORY Pathology
CPT* 88313

TEST DESCRIPTION The staining reaction is based on the reaction of Alcian Blue with a pH of 2.5 and polyanionic compounds.

Alcian Blue is a polyvalent, basic, water-soluble dye that derives its blue color from the copper phthalocyanine group which is modified with cationic solubilizing agents. During this reaction, salt linkages are formed between Alcian Blue and the acid groups of the acid mucopolysaccharides, staining them blue. The Nuclear Fast

Red Counterstain is applied to provide a pink contrasting background.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Tissu

COLLECTION CONTAINER Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- **Billing information** or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than 10% neutral buffered formalin. Paraffin blocks that have been overheated or frozen. Unlabeled/mislabeled specimens.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

 $\label{thm:conditional} \textit{Test requests can be ordered electronically through our EMR system}.$

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

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STORAGE AND TRANSPORT

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REFERENCES

REFERENCES

ALK-1 IHC STAINS

TEST INFORMATION

ALIAS Anaplastic lymphoma kinase-1

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION ALK1 (ALK01) may be used as the primary antibody for immunohistochemical staining of paraffin tissue

sections. In general, immunohistochemical staining allows the visualization of antigens via the sequential application of a specific antibody (primary antibody) to the antigen, a secondary antibody (link antibody) to the primary antibody, an enzyme complex and a chromogenic substrate with interposed washing steps. The

enzymatic activation of the chromogen results in a visible reaction product at the antigen site.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- **Billing information** or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

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STORAGE AND TRANSPORT

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REFERENCES

REFERENCES

TEST INFORMATION

 ALIAS
 AFP

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Immunoassay for the in vitro quantitative determination of α1-fetoprotein in human serum and plasma to aid

in the management of patients with non-seminomatous germ cell tumors.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

TEST INFORMATION

ALIAS Amyloid A, Amyloid P, Amyloid A&P Panel

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Amyloid A and P react with amyloid deposits in many tissues. When accompanied by Congo Red, Amyloid A and

P can be used to distinguish primary and secondary amyloidosis.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ARGINASE 1

TEST INFORMATION

ALIAS ARG1, also known as liver arginase

LABORATORY Pathology
CPT* 88342

TEST DESCRIPTION Arginase 1 (ARG1), also known as liver arginase, is a binuclear manganese metalloenzyme. ARG1 is abundantly

expressed in liver and represents a sensitive and specific marker of benign and malignant hepatocytes that may

be a useful diagnostic tool in routine surgical pathology practice.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

BAP1 IHC STAINS

TEST INFORMATION

ALIAS BRCA1-associated protein 1, Ubiquitin carboxyl-terminal hydrolase BAP1

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION BAP1 IHC stain is a tool for detection of BAP1 mutations with subsequent inactivation. Loss of BAP1 by IHC is

100% specific for malignant mesothelioma in the context of mesothelioma vs. mesothelial hyperplasia. Loss of

BAP1 may be seen in other neoplasms.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

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Request Form or e-request

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Specimen Labeling

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STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
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Please contact us with any questions, shipping label inquiries, and any special arrangements needed.

 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

BCL1 (Cyclin D1)

TEST INFORMATION

ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Cyclin D1 overexpression or amplification is associated with tumorigenesis and is detected in many cancers

including mantle cell lymphoma, breast carcinoma, lung carcinoma, and gastrointestinal neoplasms. Detection of cyclin D1 overexpression is often used to distinguish mantle cell lymphoma from chronic lymphocytic

leukemia/small lymphocytic lymphoma, which shares many other similar morphological and

immunophenotypic features. This distinction is important because mantle cell lymphoma is a more aggressive neoplasm. In addition to mantle cell lymphoma, a low number of other B-cell lymphoma cases (e.g. plasma cell

lymphoma, hairy cell leukemia, diffuse large B-cell lymphoma) express cyclin D1.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

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REFERENCES

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BCL2 IHC STAINS

TEST INFORMATION

ALIAS b cell lymphoma-2

LABORATORY Pathology

CPT* 88341, 88342, 88360

TEST DESCRIPTION The bcl-2 oncoprotein plays a central role in apoptosis, serving as an inhibitor of the apoptotic process, and it

has given name to a family of proteins engaged in the promotion/inhibition of apoptosis.1 Bcl-2 proved to block programmed cell death rather than promote proliferation. Bcl-2 is normally expressed in T cells, pre-B cells, resting B cells including normal mantle zone lymphocytes, and certain types of proliferating B cells. However, bcl-2 is down-regulated in normal germinal center B cells. Among neoplastic tissues, high bcl-2 levels are detected in most human small mature B-cell lymphomas (e.g., chronic lymphocytic leukemia/small lymphocytic lymphoma, follicular lymphoma, mantle cell lymphoma and marginal zone lymphoma), whereas it is expressed to varying degrees in diffuse large B-cell lymphoma, Hodgkin lymphoma and T-cell lymphoma. Burkitt's lymphoma is typically bcl-2-negative, although weak expression is observed in some cases.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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SPECIMEN REQUIREMENTS

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REFERENCES

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BCL6 IHC STAINS

TEST INFORMATION

ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION BCL6 antibody stains the germinal center cells in lymphoid follicles, the follicular cells and interfollicular cells in

follicular lymphoma, a subset of diffuse large B-cell lymphomas, and Burkitt lymphoma, as well as the majority of Reed-Sternberg cells in nodular lymphocyte predominant Hodgkin lymphoma. In contrast, BCL6 rarely stains mantle cell lymphoma and mucosa-associated lymphoid tissue (MALT) lymphoma. BCL6 expression is seen in approximately half of CD30+ anaplastic large cell lymphomas but is absent in other peripheral T-cell

lymphomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ **GL**, Technical Component and Professional Service or

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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REFERENCES

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BER-EP4

TEST INFORMATION

ALIAS Ep-CAM/Epithelial Specific Antigen

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Ep-CAM/Epithelial Specific Antigen (Ber-EP4) Mouse Monoclonal Primary Antibody is intended for laboratory

use in the detection of the Ep-CAM glycoprotein in formalin-fixed, paraffin-embedded human tissue stained in

qualitative immunohistochemistry (IHC).

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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REFERENCES

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BETA CATENIN IHC STAINS

ALIAS ß-Catenin

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Beta-catenin is an important regulator of cell–cell adhesion and embryogenesis. Mutations of beta-catenin

could lead to some human cancers. Normal cells show membrane staining for beta-catenin, while cytoplasmic and/or nuclear staining is abnormal. Dysregulation of beta-catenin occurs in Gardner syndrome, where it leads to both familial adenomatous polyposis and fibromatosis. Nuclear location of beta-catenin also occurs in colon and endometrioid ovarian carcinomas as well as in synovial sarcoma, osteosarcoma, liposarcoma, palisaded

myofibroblastoma, and other sarcomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE

✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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REFERENCES

REFERENCES

BOB 1

 ALIAS
 BOB1

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTIONBOB1 is present in all B-cells expressing Ig. The combination of BOB1 and OCT2 staining is helpful in

distinguishing between classical Hodgkin lymphoma (at least one marker negative) and nodular lymphocyte predominant Hodgkin lymphoma or T-cell histiocyte-rich large B-cell lymphoma (both markers expressed).

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

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REFERENCES

REFERENCES

CA19-9

 ALIAS
 CA19-9

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION In normal tissues, the CA19.9 antigen has been demonstrated in ductal epithelium of the breast, kidney,

salivary gland, sweat glands, respiratory epithelium of the lung, colon epithelium, pancreatic acini and ducts, biliary epithelium in the liver and prostate epithelium. Gastrointestinal carcinomas are positive, as well as transitional cell carcinomas of the bladder, endometrial adenocarcinomas, thyroid papillary, gallbladder carcinomas and lung carcinomas, including adenocarcinomas, bronchoalveolar cell carcinomas, squamous and

small cell carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE

✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

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REFERENCES

REFERENCES

CALCITONIN

ALIAS Calcitonin (IHC)
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTIONCalcitonin is secreted by thyroidal parafollicular cells of neuroectodermal origin, probably in response to

hypercalcemia. The IHC demonstration of calcitonin is important: (1) For identification of early or microscopic medullary thyroid cancer (MTC), (2) To identify an MTC in the absence of amyloid deposits, (3) To distinguish non-typical forms of MTC (e.g., predominantly spindle cell or small cell patterns) from anaplastic carcinoma or malignant lymphoma, (4) To differentiate MTC with microfollicular or papillary patterns from thyroid follicular and papillary neoplasms and (5) To identify C-cell hyperplasia in association with hypercalcemia of diverse

etiologies.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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REFERENCES

REFERENCES

CALDESMON

ALIAS Caldesmon
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Caldesmon is a regulatory protein found in smooth muscle and tissues which interacts with actin, myosin,

tryopomyosin and calmodulin. Caldesmon antibody detects smooth muscle and tumors of smooth muscle, myofibroblastic and myoepithelial differentiation. This antibody is also useful in the differentiation of

epithelioid mesothelioma from serous papillary carcinoma of the ovary.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 1-3 days

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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REFERENCES

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CALPONIN

ALIAS Calponin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Calponin, a calmodulin, is involved in the regulation of smooth muscle contraction. The expression of calponin

is restricted to smooth muscle cells. Two isoforms of calponin exist with molecular weights of 34kDa and 29kDa. Expression of the 29kDa form is primarily restricted to muscle of the urogenital tract. Calponin also labels myoepithelial cells and can be useful in distinguishing in situ from infiltrating breast carcinoma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS n/a

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REFERENCES

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CALRETININ

ALIAS Calretinin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Calretinin is the most specific and reproducible positive marker of epithelial mesothelioma. Calretinin is a

calcium-binding protein similar to S100 protein. It is found in the central and peripheral nervous system and in a wide spectrum of non-neural cells, including steroid-producing cells of ovaries and testes, fat cells, renal tubular epithelial cells, eccrine glands, thymic epithelial cells and mesothelial cells. Calretinin immunostaining is

found in most epithelial mesotheliomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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SPECIMEN REQUIREMENTS

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Attn: Accessioning Department

REFERENCES

REFERENCES

ALIAS Cytokeratin LMW
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Anti-Cytokeratin (CAM 5.2) has a primary reactivity with human keratin proteins that correspond to Moll's

peptides #7 and #8, Mr 48 and 52 Kd. Cytokeratin 8 is present on secretory epithelia of normal human tissue but not on stratified squamous epithelium. CAM 5.2 stains most epithelial derived tissue, including liver, renal tubular epithelium, hepatocellular and renal cell carcinomas. CAM 5.2 may not react with some squamous cell

carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

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CAUSES FOR REJECTION

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REFERENCES

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ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Carbonic anhydrase IX (CAIX) is a cell surface transmembrane protein, which is predominantly found in the

gastrointestinal tract and gall bladder. The glandular regions of normal colon are reported to be negative, but in the case of adenocarcinoma, the glands are positive. CAIX is also expressed in common epithelial tumors such as carcinomas of the esophagus, lung, colon, kidney, cervix, and non-small cell lung carcinoma (NSCLC). In breast carcinomas, CAIX expression is associated with malignant tissue. Expression of CAIX is absent in normal kidney, chromophobe carcinomas or oncocytomas; however, it is specifically expressed in clear cell renal

carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

CA125

 ALIAS
 CA125

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CA125 reacts with most epithelial ovarian neoplasms of serous, endometrioid, clear cell and undifferentiated

types. CA125 is a useful tumor marker for ovarian carcinomas; however, CA125 has also been described in other neoplasms such as seminal vesicle and anaplastic lymphomas. No reactivity has been shown for mucinous ovarian tumors. It reacts with both normal tissues and neoplasms of fallopian tube, endometrium, endocervix and mesothelioma. It does not react with colon cancer. Normal tissues such as breast, liver, skin,

kidney and spleen are negative.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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CD1a IHC STAINS

ALIAS CD1a
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION At least five CD1 genes (CD1a, b, c, d, and e) have been identified. CD1a is expressed on cortical thymocytes,

Langerhans cells, and dendritic cells. It is absent on mature peripheral blood T-cells, but cytoplasmic expression is detected on activated T-lymphocytes. CD1a is found on a subset of T-lymphoblastic lymphoma-leukemia and

cases of Langerhans cell histiocytosis.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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 ALIAS
 CD2

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD2, the E-rosette receptor, is an extremely broad T-cell marker. This antibody immunostains the vast majority

of T-cells and a subset of natural killer (NK) - cell malignancies. Half of thymic B-cells are also CD2 positive.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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ALIAS CD3
LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION The CD3 antigen is first detectable in early thymocytes and its appearance probably represents one of the

earliest signs of commitment to the T-cell lineage. It has a cytoplasmic expression at early T-cell differentiation, then membranous expression. CD3 is the most specific T-cell antibody. CD3 is expressed in normal thymocytes,

peripheral T-cells, NK cells, and Purkinje cells of cerebellum. In diseased cells, CD3 stains most T-cell

lymphomas. Only rare B cell lymphomas may be positive for CD3.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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CD4 (T cell)

 ALIAS
 CD4 (T cell)

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD4, a single chain transmembrane glycoprotein, is found on a T-cell subset (helper/inducer). It is also present

on a variety of monocyte-derived cells, including Langerhans and other dendritic cells. The CD4 epitope is absent from immature thymocytes and is expressed during T-cell development. Precursor T-lymphoblastic lymphomas are therefore variable in their expression of CD4, but most mature T-cell lymphomas are positive, with the exception of aggressive NK-cell leukemia, extranodal NK-cell lymphoma, gamma delta T-cell

lymphomas, and enteropathy-type T-cell lymphoma.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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 ALIAS
 CD5

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD5, a transmembrane protein, is found on most thymocytes and immature peripheral T-cells. It stains normal

B-cells of mantle zone of spleen and lymph nodes, B-cells in peritoneal and pleural cavities, and almost all T-cells. In a fetus, most B-cells in spleen and cord blood are CD5 positive. It stains B-cell chronic lymphocytic leukemia/ small lymphocytic leukemia (CLL/SLL), mantle cell lymphoma (MCL), hairy cell leukemia (HCL), most

T-malignancies, and most thymic carcinomas. CD5 is usually negative in spindle cell thymoma.

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REFERENCES

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 ALIAS
 CD7

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD7 is expressed on the majority of immature and mature T-lymphocytes and T-cell leukemia. It is also found

on natural killer cells, and a small subpopulation of normal and malignant B-cells. CD7 antibody can be useful for detection of T-cell leukemias and myeloid leukemias. CD7 expression is often lost in mycosis fungoides.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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 ALIAS
 CD8

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD8 is a T-cell marker for the detection of cytotoxic/suppressor T-cells. CD8 is also detected on NK cells, most

thymocytes, a subpopulation of null cells, and bone marrow cells. This antibody is useful in evaluating T-cell

lymphomas.

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REFERENCES

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ALIAS CD10, Common Acute Lymphocytic Leukemia Antigen (CALLA)

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD10, also known as Common Acute Lymphocytic Leukemia Antigen (CALLA), is expressed in early lymphoid

progenitors and normal germinal center cells. It is almost always present on the surface of precursor B-lymphoblastic and Burkitt lymphomas and much less frequently on precursor T-lymphoblastic leukemia-lymphoma. Many follicular lymphoma and some diffuse large B-cell lymphomas, along with multiple myeloma are positive. CD10 is also present on breast myoepithelial cells, bile canaliculi, fibroblasts and with especially high expression on the brush border of kidney and gut epithelial cells. CD10 is also a good marker of

endometrial stomal sarcoma.

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REFERENCES

REFERENCES

CD14 IHC STAINS

 ALIAS
 CD14

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD14 stains normal macrophages/monocytes, granulocytes (weak), Langerhans cells, dendritic cells, and B

cells. Positive staining in diseased cells comprises B-cell chronic lymphocytic leukemia (B-CLL), follicular center

cell lymphoma, diffuse large B cell lymphoma (DLBCL), and acute myeloid leukemia (AML)-M4/M5.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ **GL**, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

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CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

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STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

 ALIAS
 CD15

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD15 (X-Hapten) plays a role in mediating phagocytosis, bactericidal activity, and chemotaxis. It is present on

granulocytes, including neutrophils and eosinophils, and to a lesser degree on monocytes. CD15 is also expressed in Reed-Sternberg cells and some epithelial cells. CD15 antibody is useful in the identification of Hodgkin lymphoma. CD15 is occasionally expressed in large cell lymphomas of both B- and T- phenotypes.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

CD19 IHC STAINS

 ALIAS
 CD19

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD19 recognizes a 95kD cell surface glycoprotein which is expressed by cells of the B-cell lineage and follicular

dendritic cells. CD19 is a co-receptor of CD21 and is an important signal transduction molecule which is involved in the regulation of B-lymphocyte development, activation and differentiation. CD19 may provide useful

diagnostic information for the study of B-lymphoproliferative disorders.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD20

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Normal cell expression of CD20 is found on most B-cells (after CD19 and CD10 expression, before CD21/22

expression and surface immunoglobulin expression) and expression is retained on mature B-cells until plasma cell development, as well as ollicular dendritic cells. In diseased cells, there is positive staining on most B-cell lymphomas, come pre-acute B lymphoblastic leukemia/ lymphoblastic lymphoma (B-ALL/LBL); lymphocyte predominant Hodgkin lymphoma, dimly expressed in T-cells (benign and neoplastic), and spindle cell

thymomas. Rixtuximab treated patients may lose CD20 positivity in B cell lymphomas.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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 ALIAS
 CD21

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD21 (CR2, C3d receptor and EBV receptor) is expressed strongly on mature B-cells, follicular dendritic cells

(FDC) and weakly on immature thymocytes and T-lymphocytes. In B-cell ontogeny, CD21 appears after the pre-B-stage, is maintained during peripheral B-cell development and is lost upon terminal differentiation into plasma cells. Immunohistological analysis of FDC in paraffin sections of Non-Hodgkin lymphoma (NHL) with this antibody demonstrates a nodular and usually dense and sharply defined FDC meshwork in follicular lymphomas and a loose, ill-defined FDC of varying size in some diffuse lymphoma types. Precursor B-cell lymphoma (lymphoblastic lymphomas), Burkitt lymphomas, plasmacytomas and hairy cell leukemias consistently lack

CD21 expression. CD21 is expressed on follicular dendritic cell sarcoma.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

CD23 IHC STAINS

 ALIAS
 CD23

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD23 is identical to low affinity IgE receptor found on B-cells. CD23 is expressed on a subpopulation of

peripheral blood cells, B-lymphocytes and on EBV transformed B-lymphoblastoid cell lines. CD23 is most useful in distinguishing B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) from other

entities and may remain present in CLL/SLL that has undergone large cell transformation.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD30

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD30 is a lymphocyte activation antigen, related to tumor necrosis factor. It is expressed in activated B-, T- and

NK cells. Positive staining is seen in infectious mononucleosis, lymphocytes infected with HIV, HTLV-1, EBV, HHV8 or hepatitis B, Reed-Sternberg cells, anaplastic large cell lymphomas (90%), lymphomatoid papulosis,

peripheral T-cell lymphomas, and embryonal cell tumors.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD31

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD31 is a 130kDa transmembrane glycoprotein that is shared by vascular lining cells, megakaryocytes and

platelets. This marker is highly restricted to endothelial neoplasms among all tumors of the soft tissue and its sensitivity is excellent. 100% of angiosarcomas and hemangiomas are CD31 positive. However, Kaposi's sarcoma (KS) is labeled more consistently by CD34 than by CD31. CD31 has also been used as a prognostic

marker measuring tumor angiogenesis. CD31 also stains histiocytes.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

CD33 IHC STAINS

 ALIAS
 CD33

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD33 is a useful marker to identify cells of myeloid and monocytic lineage, leukemias and myeloproliferative

neoplasms derived from these cells.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

REFERENCES

CD34 IHC STAINS

ALIAS CD34
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD34, a single chain transmembrane glycoprotein, is selectively expressed on human lymphoid and myeloid

hematopoietic progenitor cells and endothelial cells. CD34 antibody labels many gastrointestinal stromal tumors (GIST), dermatofibrosarcoma protuberans, solitary fibrous tumor and a subset of sarcomas. CD34

staining has been also used to measure angiogenesis.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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CD35 IHC STAINS

 ALIAS
 CD35

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD35 antigen is a transmembrane protein of 160-250 kDa that binds complement components C3b and C4b. It

mediates phagocytosis by neutrophils and monocytes. CD35 is found on erythrocytes, B-cells, a subset of T-cells, monocytes, macrophages cultured in vitro, neutrophils, eosinophils, glomerular podocytes and follicular dendritic cells. CD35 antibody is useful in the diagnosis of mucosa-associated lymphoid tissue (MALT) lymphoma and in the study of inflammatory disorders. It also labels follicular dendritic cell sarcoma.

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REFERENCES

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 ALIAS
 CD35

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD43 (leukosialin, sialophorin, or leukocyte sialoglycoprotein) is a cell surface glycoprotein that is expressed on

all thymocytes, T-cells, and cells of myeloid lineage. CD43 antibody can be useful in the diagnosis of T-cell lymphoma and a subset of B-cell lymphoma. CD43 expression in lymphomas is highly correlated with CD5; thus, most T-cell malignancies and a group of small lymphocyte B-cell malignancies (CLL/SLL, mantle cell lymphoma, and prolymphocytic leukemia (PLL)) are often positive, whereas follicular lymphoma is rarely positive. CD43 is

also positive in about 50% of cases of Burkitt lymphoma.

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CAUSES FOR REJECTION

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COLLECTION AND TRANSPORT

COLLECTION

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Attn: Accessioning Department

REFERENCES

REFERENCES

CD44 IHC STAINS

 ALIAS
 CD44

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION The CD44 family of glycoproteins exists in a number of variant isoforms, including hematopoietic variant

(CD44s) and epithelial cells variant (CD44v). While many human tumors express CD44, a positive correlation between increased CD44 expression and tumor progression has been demonstrated in only some. The most practical application of CD44 immunostaining at present is the discrimination of urothelial transitional cell

carcinoma-in-situ from non-neoplastic changes in the urothelium.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

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REFERENCES

REFERENCES

CD45/LCA IHC STAINS

ALIAS CD45/LCA
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD45 (Leukocyte Common Antigen, LCA) is comprised of at least four isoforms (CD45RA, CD45RB, CD45RC and

CD45RO) of membrane glycoproteins. CD45 is expressed on hematopoietic cells (human leukocytes, including lymphocytes, monocytes, and eosinophils), but is absent on normal and malignant non-hematopoietic tissues.

Immunohistochemistry (IHC)

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SPECIAL INSTRUCTIONS

METHODOLOGY

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REFERENCES

REFERENCES

ALIAS CD56
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD56 recognizes two proteins of the neural cell adhesion molecule, the basic molecule expressed on most

neuroectodermally-derived cell lines, tissues and neoplasms (e.g. retinoblastoma, medulloblastomas, astrocytomas, and neuroblastomas). It is also expressed on some mesodermally-derived tumors (rhabdomyosarcoma) and on natural killer cells. CD56 can be used as a marker for NK cell neoplasms. Some benign and malignant plasma cells are also positive. CD56 is often positive in neuroendocrine carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD57

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD57 is expressed on subpopulations of peripheral blood mononuclear cells, NK active cells and T-cells.

Hematopoietic malignancies that are CD57+ include a minority of T-lymphoblastic leukemias, roughly three quarters of the indolent T-cell large granular lymphocytic leukemias, and a small portion of NK-cell lymphomas. It can be used to highlight small lymphoid cells in nodular lymphocytic predominant Hodgkin lymphoma.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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CD68 KP1

 ALIAS
 CD68 KP1

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD68 is an antibody directed against lysosomes. It is important for identifying macrophages in tissue sections. It

stains macrophages in a wide variety of human tissues, including Kupffer cells and macrophages in the red pulp of the spleen, lamina propria of the gut, lung alveoli, and bone marrow. This antibody reacts with myeloid precursors and peripheral blood granulocytes. It shows strong granular cytoplasmic staining of chronic and acute myeloid leukemia and also reacts with true histiocytic neoplasia. It also stains granular cell tumors and some cases of melanoma, renal cell carcinoma, and pleomorphic sarcoma. Tumors of lymphoid origin are

usually not stained.

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REFERENCES

REFERENCES

CD68 PGM1

ALIAS CD68 PGM1
LABORATORY Pathology
CPT* 88341, 88342
TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

CD79a IHC STAINS

ALIAS CD79a
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD79a first appears at the pre B-cell stage and persists until the plasma cell stage where it is found as an

intracellular component. CD79a is found in the majority of acute leukemias of precursor B-cell type, B-cell lines,

B-cell lymphomas, and in some myelomas. It is not present in myeloid cells or T-cells.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD99

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD99 (MIC2 gene product, E2) antigen is strongly expressed by Ewing sarcoma cells, primitive peripheral

neuroectodermal tumors, and lymphoblastic leukemia/lymphoma.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

ALIAS CD117
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD117 (cKit) is a transmembrane receptor tyrosine kinase. It is expressed in many tissues and cells, such as

tissue mast cells, skin basal cells, melanocytes, breast glandular epithelial cells, dermal sweat gland, esophageal glands, testicular and ovarian interstitial cells. Abnormal expression of cKit has been implicated in pathogenesis of myeloid leukemias. cKit expression has also been demonstrated in solid tumors including gastrointestinal

stromal tumor (GIST), melanomas, breast carcinomas and small cell lung carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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SPECIAL INSTRUCTIONS

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REFERENCES

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ALIAS CD123
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CD123 labels plasmacytoid dendritic cells and is useful in diagnosing neoplasms derived from these cells as well

as reactive conditions, such as histiocytic necrotizing lymphadenitis.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD138

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD138 (Syndecan-1) positively stains normal tissue including B-cell precursors and plasma cells. Positive

staining in tumors includes myeloma, primary effusion lymphoma. CD138 negative staining comprises mature

B-cells and lymphomas (even plasmacytoid lymphomas). Many carcinomas also express CD138.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

 ALIAS
 CD163

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION CD163 antigen is restricted in its expression to the monocytic/macrophage lineage. It is present on all

circulating monocytes and most tissue macrophages except those found in the mantle zone and germinal

centers of lymphoid follicles, interdigitating reticulum cells and Langerhans cells.

METHODOLOGY Immunohistochemistry (IHC)

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SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

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CAUSES FOR REJECTION

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COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

CD246 (ALK) IHC STAINS

ALIAS CD246 (ALK)

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Need info

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

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REFERENCES

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CDX-2

ALIAS CDX-2
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CDX2 is an intestine specific transcription factor that regulates both the proliferation and differentiation of

intestinal epithelial cells. It is expressed in the nuclei of epithelial cells throughout the intestine, from duodenum to rectum. The CDX2 protein is expressed in primary and metastatic colorectal carcinomas and has also been demonstrated in the intestinal metaplasia of the stomach and intestinal-type gastric cancer. It is not expressed in the normal gastric mucosa. CDX2 may be used in identifying metastatic carcinoma of colonic or

other gastrointestinal tract origin in the setting of an unknown primary tumor.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

REFERENCES

CEA (M)

ALIAS CEA (Monoclonal)

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Carcinoembryonic antigen (CEA) is usually demonstrated as a linear labeling of the apical poles of cells lining

the glandular lumen and occasionally as weak staining near the apex of normal colonic epithelial cells. Tumors tend to display an increased cytoplasmic staining. In specific cases, CEA can be useful in tumor diagnosis. Pancreatic carcinomas, testicular tumors, gallbladder neoplasms and granular cell myoblastomas all stain positive for CEA, while malignant tumors of brain, prostate, skin, lymphoreticular tissues, hepatocellular

carcinomas, esophageal squamous cell carcinomas and mesothelioma fail to stain for CEA.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

REFERENCES

CEA (P)

ALIAS CEA (Polyclonal)

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Polyclonal carcinoembryonic antigen (CEA) antibody stains a larger percentage of cholangiocarcinomas

compared to hepatocellular carcinomas. Approximately 95% of olangiocarcinomas are stained diffusely and

strongly with polyclonal CEA, whereas show a canalicular staining pattern with this antibody.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

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needed.

ALIAS Chromogranin A
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Chromogranin is present in several elements of the diffuse neuroendocrine system (DNES), including anterior

pituitary, thyroid perifollicular C cells, parathyroid chief cells, pancreatic islet cells, intestinal enterochromaffin cells and tumors derived from these cells. Chromogranin immunoreactivity was also seen in thymus, spleen, lymph nodes, fetal liver, neurons, the inner segment of rods and cones, the submandibullar gland and the

central nervous system. This marker is useful in evaluating neuroendocrine tumors.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

REFERENCES

CK 5/6

ALIAS Cytokeratin 5/6
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION D5/16 B4 clone of CK5/6 antibody reacts strongly with cytokeratins 5 and 6. Cytokeratin 5/6 have been found

valuable for the distinction between low differentiated squamous cell carcinoma and adenocarcinoma. It labels mesothelioma, and epithelial basal cells in prostate and tonsil. No reactivity with other mesodermally derived tissues, such as muscle and connective tissues, has been observed. Anti-CK 5/6 has also been found useful in

the differential diagnosis of atypical proliferations of the breast.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

REFERENCES

CK 7

ALIAS Cytokeratin 7
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Cytokeratin 7 (CK7) antibody reacts with proteins that are found in most ductal, glandular and transitional

epithelium of the urinary tract and bile duct epithelial cells. CK7 distinguishes between lung and breast epithelium that stain positive, and colon and prostate epithelial cells that are negative. It also reacts with many benign and malignant epithelial lesions, e.g. adenocarcinomas of the ovary, breast and lung. Transitional cell carcinomas are positive and most prostate cancers are negative. This antibody does not recognize other

intermediate filament proteins.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

REFERENCES

CK19

ALIAS Cytokeratin 19
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Cytokeratin 19 (CK19) is a member of the type I acidic subfamily of keratins. It is expressed in various, different

human tissues. CK19 labels ductal and glandular epithelia, prostatic epithelia, and non-keratinizing squamous epithelia. This antibody is useful in the diagnosis of breast and cervical carcinoma. CK19 is not expressed in hepatocytes, therefore, antibody to CK19 is also useful in the distinction of liver metastasis from hepatocellular

carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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SPECIMEN REQUIREMENTS

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REFERENCES

REFERENCES

CK20

ALIAS Cytokeratin 20
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Cytokeratin 20 (CK20) positivity is seen in the majority of adenocarcinomas of the colon, mucinous ovarian

carcinomas, transitional cell, and Merkel cell carcinomas, and frequently in adenocarcinomas of the stomach, bile system and pancreas. CK7/CK20 immunostaining patterns may be helpful in separating pulmonary from

colonic adenocarcinomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

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ALIAS Cytokeratin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CK903 (34betaE12) is a high molecular weight cytokeratin present in all squamous epithelium and their

carcinomas. This antibody recognizes cytokeratins 1, 5, 10 and 14 that are found in complex epithelia. There has been no reactivity with cells derived from simple epithelia, mesenchymal tumors, lymphomas, melanomas, neural tumors and neuroendocrine tumors. One useful application is the identification of the basal cell layer in

prostate tissue in the determination of carcinoma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24 – 48 hours

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REFERENCES

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ALIAS Cytomegalovirus

LABORATORY Pathology

CPT* 88365

TEST DESCRIPTION Cytomegalovirus (CMV) is an opportunistic pathogen infecting lung, kidney, gut, and other organs in situations

where an individual is immunologically immature, such as the fetus and neonate. Infection also occurs in immunosuppressed patients, e.g. transplant patients, patients undergoing chemotherapy and HIV infected

patients.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 48-72 hours

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SPECIMEN REQUIREMENTS

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 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

C-MYC IHC STAINS

ALIAS CMYC
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION CMyc protein is a transcription factor localized to the nucleus of the cell. Amplification of the cMyc

gene has been found in several types of human tumors. cMyc is amplified in 20-30% of breast cancer cases and is associated with HER-2 amplification and poor outcome. In Burkitt's lymphoma, 90% of tumors have translocation of cMyc or variants. cMyc protein (>50%) is seen in a subset of cases of diffuse large B-cell lymphoma (DLBCL) and is correlated with *Myc* rearrangement. It is also

positive in radiation-associated angiosarcoma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 48-72 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

▼ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- · Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

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Request Form or e-request

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If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
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REFERENCES

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CONGO RED IHC STAINS

ALIAS Congo Red
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Special stain. Amyloidosis is a rare disease characterized by the deposition of insoluble misfolded proteins in

various tissues and organs. Congo red stain is the gold standard for the demonstration of amyloid in tissue sections. The amyloid fibril Congo red complex demonstrates "apple green" birefringence using polarized light microscopy. For cases with positive Congo red staining, immunohistochemical stains for amyloid A, amyloid P and immunoglobulin light chains are available for further evaluation of the amyloid subtype, if clinically

indicated.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

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REFERENCES

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CRYSTAL VIOLET

ALIAS Crystal Violet
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Special Stain. Crystal violet is also used in the microscopic examination of cells to highlight and give contrast to

specific features of the cell, e.g. nuclei and cytoplasm.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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SPECIMEN REQUIREMENTS

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REFERENCES

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 ALIAS
 D240

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION D2 40 identifies a 40kDa O-linked sialoglycoprotein expressed by a variety of tissues, including fetal testes and

testicular germ cell tumors. Anti-D2 40 has also been demonstrated to label lymphatic endothelium whereas it is unreactive with vascular endothelium. In neoplastic tissue, immunostaining of lymphatic endothelium by anti-D2 40 can be useful in identifying lymphatic invasion of primary tumors. It is also often positive on

sarcomatoid malignant mesothelioma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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DESMIN IHC STAINS

ALIAS Desmin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Desmin is an intermediate filament protein of both smooth and striated muscles. Antibody to desmin reacts

with striated (skeletal and cardiac) as well as smooth muscle cells. Anti-desmin antibody is useful in identification of tumors of myogenic origin. It reacts with leiomyosarcomas (smooth muscle) as well as

rhabdomyosarcomas (striated muscle).

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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SPECIMEN REQUIREMENTS

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REFERENCES

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DOG1

 ALIAS
 Dog1

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION DOG1 is a cell surface protein of unknown function selectively expressed in gastrointestinal stromal tumors

(GIST). Among GIST cases with Kit mutations the DOG1 antibody identified 11% more cases than c-Kit antibody. DOG1 identifies the vast majority of both cKIT negative and Platelet-derived Growth Factor Receptor Alpha (*PDGFRA*) mutated GIST cases that may still benefit from imatinib mesylate (Gleevec*), an inhibitor of the Kit tyrosine kinase. In addition, DOG1 immunoreactivity is seen in fewer cases of mesanchymal, epithelial tumors and melanomas when compared with cKIT. The use of this highly sensitive and specific novel marker will

increase the accuracy of GIST diagnosis.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

DPC4 (SMAD4)

ALIAS SMAD4
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION The gene *DPC4* (deleted in pancreatic carcinoma 4, also called SMAD4) was identified in 18q21.3 This gene is

frequently mutated and deleted in pancreatic carcinomas (55%) and less frequently (20 - 22%) in colon carcinomas. Loss of expression is specific for pancreatic malignancy (in-situ or invasive) vs. benign process,

particularly helpful in biopsies.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

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REFERENCES

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ALIAS EBV
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION This antibody reacts strongly with Epstein Barr Virus (EBV)-positive lymphoblastoid cell lines and EBV infected

B-cell immunoblasts in infectious mononucleosis. It also reacts with some EBV-associated neoplasms,

particularly EBV-associated Hodgkin lymphoma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

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REFERENCES

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E-CADHERIN IHC STAINS

ALIAS E-Cadherin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION E Cadherin is an adhesion protein that is expressed in cells of epithelial lineage. It stains positively in glandular

epithelium, as well as adenocarcinomas of the lung, G.I. tract and ovary. It is useful in distinguishing adenocarcinoma from mesothelioma. It is also positive in some thyroid carcinomas. Breast carcinomas with ductal and lobular features show two staining patterns: (1) complete or almost complete lack of membrane staining in lobular carcinomas and (2) uniform membrane expression throughout the tumor in ductal carcinomas. Immunohistochemical detection of ECadherin expression can be a useful diagnostic tool for the

differentiation of ductal and lobular carcinomas of the breast.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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SPECIMEN REQUIREMENTS

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REFERENCES

REFERENCES

EGFR IHC STAINS

ALIAS EGFR
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Epidermal Growth Factor Receptor (EGFR) overexpression can occur in a variety of tumor types, including

breast, prostate, ovarian, brain, lung and predominantly squamous cell carcinomas. Tumors that express EGFR are associated with a poor prognosis and a shorter disease-free survival. Most colon carcinomas will show expression of EGFR in more than 1% of the invasive tumor cells. Patients whose tumor expresses EGFR are eligible for cetuximab therapy although the response to therapy is independent of the intensity or percentage

of cells staining.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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LEVELS OF SERVICE

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✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

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REFERENCES

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EMA IHC STAINS

ALIAS Epithelial Membrane Antigen

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Epithelial Membrane Antigen (EMA) antibody stains normal and neoplastic cells from various tissues, including

mammary epithelium, sweat glands and squamous epithelium. Hepatocellular carcinoma, adrenal carcinoma and embryonal carcinomas are consistently EMA negative, therefore, keratin positivity with negative EMA favors one of these tumors. EMA is frequently positive in meningioma, which can be useful when distinguishing it from other intracranial neoplasms, e.g. Schwannomas. The absence of EMA can also be of value since negative EMA is characteristic of tumors such as adrenal carcinoma, seminomas, paraganglioma and

hepatoma.

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

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REFERENCES

REFERENCES

ALIAS Monoclonal antibody MOC 31

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Monoclonal antibody MOC31 recognizes a membrane glycoprotein of 40kDa present on epithelial cells but not

on mesothelial cells. MOC31 reacts with most adenocarcinomas of various origins, typically with strong staining pattern. Only rare cases of mesotheliomas show focal or weak staining. MOC31 antibody does not label liver as well as hepatocellular carcinoma, therefore, it will be helpful in the differential diagnosis of liver metastases

versus hepatocellular carcinomas.

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SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

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CAUSES FOR REJECTION

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COLLECTION AND TRANSPORT

COLLECTION

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

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ER IHC STAINS

ALIAS Estrogen Receptor

LABORATORY Pathology

CPT* 88341, 88342, 88360, 88361

TEST DESCRIPTION Estrogen Receptor (ER) belongs to a superfamily of nuclear hormone receptors and is expressed in about 85%

of invasive breast cancers. There are two known isoforms of estrogen receptor, $ER\alpha$ and ERB. It is a weak prognostic factor but a strong predictive factor for response to endocrine therapies, both in adjuvant and metastatic settings. The primary indication to assess ER in breast cancer is to predict response to hormonal therapies such as tamoxifen, other selective estrogen receptor modulators (SERMs) and aromatase inhibitors. In univariate analysis, moderate to strong staining in even 1% of the invasive tumor cells is associated with significant improvement in disease-free survival compared to those patients whose tumor lacks ER expression.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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ERG IHC STAINS

ALIAS ERG
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION ERG oncoprotein expression has been shown to be a highly specific marker for prostate cancer. Given the lack

of ERG expression in a wide variety of normal epithelial tissues and tumors, detection of ERG by IHC is a valuable tool for diagnosing prostate cancer or determining prostatic origin. ERG is also a highly specific and

sensitive marker of endothelial cells and vascular tumors.

METHODOLOGY Immunohistochemistry (IHC)

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FACTOR 13

ALIAS Factor XIIIa

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Factor XIIIa is a dermal dendrocyte marker and shows variable reaction with these types of tumors. It can be

used for histiocytic phenotyping and has been reported to mark capillary hemangiomas and tumors of the central nervous system. Factor XIIIa has also been used with CD34 to differentiate between dermatofibroma

and dermatofibrosarcoma protuberans.

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ALIAS Factor VIII (von Willebrand Factor [VWF])

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Factor VIII-related antigen is a component of Factor VIII complex. Factor VIII-related antigen is one of the

available immunohistochemical markers of endothelial cells. It has also been demonstrated in platelets and megakaryocytes. IHC staining of Factor VIII-related antigen is useful for diagnosis of vascular neoplasms and for

identification of vascular invasion by neoplasms.

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FASCIN

ALIAS Fascin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Human fascin is a highly conserved actin-bundling protein. It is expressed predominantly in dendritic cells.

Lymphoid cells, myeloid cells and plasma cells are negative for staining. However, Reed-Sternberg cells in

Hodgkin lymphoma are positive for fascin staining. Epstein-Barr virus may induce expression of fascin in B-cells.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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needed.

FEULGEN IHC STAINS

ALIAS Feulgen
LABORATORY Pathology
CPT* 88341, 88342
TEST DESCRIPTION Need Info

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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FITE

ALIAS Fite (Leprosy) Stain

LABORATORYPathologyCPT*88341, 88342TEST DESCRIPTIONSpecial Stain

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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GALECTIN-3

ALIAS Galectin-3
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Galectins are a structurally-related family of proteins; 14 different galectins have been characterized. They are

cytoplasmic proteins and can be translocated into the nucleus. Gal-3 has been found overexpressed in most malignant thyroid neoplasms. However, it was not detectable in normal and non-malignant tissue. Galectin 3 is

a useful marker to differentiate benign from malignant (Galectin 3-positive) thyroid neoplasms.

METHODOLOGY Immunohistochemistry (IHC)

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GASTRIN

ALIAS Gastrin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Gastrin, a polypeptide hormone, occurs naturally in three forms: gastrin-14, gastrin-17 and gastrin-34. This

antibody labels gastrin or gastrin-analogue producing cells in gastrin-secreting tumors and G cell hyperplasia.

METHODOLOGY Immunohistochemistry (IHC)

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GATA3 IHC STAINS

ALIAS GATA binding protein 3

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION GATA3 (GATA binding protein 3) is a member of the GATA family of transcription factors. Among several other

roles, GATA3 is involved in luminal cell differentiation in the mammary gland and appears to control a set of genes involved in the differentiation and proliferation of breast cancer. The expression of GATA3 is associated with the expression of estrogen receptor-alpha (ER) in breast cancer. GATA3 has been shown to be a novel marker for bladder cancer. GATA3 stains almost all of urothelial carcinomas, but stained no prostate or renal

carcinomas.

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GCDFP 15

ALIAS Gross Cystic Disease Fluid Protein

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION This antibody is specific to a 15kDa monomer protein called Gross Cystic Disease Fluid Protein-15 (GCDFP-15).

GCDFP15 is expressed in apocrine epithelia, lacrimal, ceruminous and Moll's glands, as well as in numerous serous cells of the submandibular, tracheal, bronchial, sublingual and minor salivary glands. It can be of use in

the identification of breast carcinoma, salivary duct carcinoma and apocrine epithelia.

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GFAP IHC STAINS

ALIAS Glial Fibrillary Acidic Protein

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Glial Fibrillary Acidic Protein (GFAP) is the major protein found in astrocytes and its expression is evidence of

astroglial origin and differentiation. Gliomas are the most common cerebral neoplasm in adults and include astrocytomas, oligodendrogliomas and glioblastomas. It can also be demonstrated in ependymal cells, ependymomas, subependyomas, glioblastomas, mixed central nervous system neoplasms and gangliomas. It is detected in immature but not mature oligodendrocytes and neurons. Anti-GFAP antibodies do not cross-react with neurons, fibroblasts, or muscle cells. Anti-GFAP antibodies are useful in differentiating primary gliomas from metastatic lesions in the brain and for documenting astrocytic differentiation in tumors outside the

central nervous system.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% ne

10% neutral buffered formalin

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

SPECIAL INSTRUCTIONS

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

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Request Form or e-request

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Specimen Labeling

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STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

GLUT1 IHC STAINS

ALIAS Glucose transporter 1

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Glucose transporter 1 (GLUT1) facilitates the transport of glucose across the plasma membranes of mammalian

cells. GLUT-1 is expressed in many human tissues including those of the colon, lung, stomach, esophagus and breast. Overexpression of GLUT1 is associated with aggressive behavior in some cancers, including breast, renal, and bladder carcinoma. Expression of GLUT1 can help distinguish malignant mesothelioma from reactive

mesothelial proliferations.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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GLYCOPHORIN A IHC STAINS

ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Glycophorin A (sialoglycoprotein alpha) is one of two transmembrane proteins exposed on the outer surface of

normal human erythrocytes. This monoclonal antibody reacts with an epitope located on the extracellular domain of glycophorin A and does not cross-react with glycophorin D (glycophorin delta). In normal human erythrocytes, glycophorin A is expressed during all stages of differentiation, from the normoblast to the mature erythrocyte. Once maximally expressed, the quantity of glycophorin A in each red blood cell remains constant. Glycophorin A has also been located in the blast cells of cases of erythroleukemia. Cases of acute lymphoblastic

and myeloblastic leukemia are not reactive.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

GLYPICAN3 IHC STAINS

 ALIAS
 GC33

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION A useful marker to differentiate between benign (negative) and malignant (positive) liver diseases (HCCs).

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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GMSIHC STAINS

ALIAS Grocott Methanamine Silver (GMS)

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Special stain. GMS (Grocott Methenamine-Silver Nitrate) Fungus Stain is used to demonstrate fungal organisms

in tissue sections.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 48-72 hours

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SPECIMEN REQUIREMENTS

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COLLECTION CONTAINER 10% neutral buffered formalin

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REFERENCES

REFERENCES

GRAM STAIN (-)

ALIAS Gram Stain (-)
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Gram Staining Kit is intended for use as a qualitative histologic stain to demonstrate gram-negative and gram-

positive bacteria in formalin-fixed, paraffin-embedded tissue.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 48-72 hours

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REFERENCES

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 ALIAS
 Gram Stain (+)

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Gram Staining Kit is intended for use as a qualitative histologic stain to demonstrate gram-negative and gram-

positive bacteria in formalin-fixed, paraffin-embedded tissue.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 48-72 hours

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REFERENCES

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ALIAS HepPar1

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Anti-Hepatocyte Specific Antigen (HepPar1) recognizes both benign and malignant liver derived tumors such as

hepatoblastoma, hepatocellular carcinoma and hepatic adenoma. It recognizes both adult and fetal liver tissue. The typical pattern is a granular cytoplasmic staining. This antibody is useful in differentiating hepatocellular carcinomas from adenocarcinomas, either primary or metastatic. HepPar1 also can be used in differential diagnostic separation of hepatoblastoma versus other small round cell tumors. HepPar1 is also expressed in a

subset of gastric carcinoma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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LEVELS OF SERVICE

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SPECIMEN REQUIREMENTS

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REFERENCES

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HBME

ALIAS HBME
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION HBME1 is an anti-mesothelial monoclonal antibody that recognizes an unknown antigen on the microvilli of

mesothelioma cells. It stains normal mesothelial cells as well as epithelial mesotheliomas in a thick membrane

pattern. This antibody also reacts with some carcinomas showing cytoplasmic immunostaining.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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HCG IHC STAINS

ALIAS Human Chorionic Gonadotropin (HCG)

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION HCG-beta is secreted in large quantities by the placenta and normally is found in maternal circulation during

early fetal development. Polyclonal Rabbit Anti-Human Chorionic Gonadotropin is intended for use in immunocytochemistry. The antibody labels hCG-containing cells and may be used for the demonstration of

trophoblastic elements, e.g. in germ cell tumors.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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ALIAS Her-2 Neu (Cerb-2 Onco Protein)

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody (PATHWAY anti-HER2 (4B5) antibody) is

a rabbit monoclonal antibody intended for laboratory use for the semiquantitative detection of HER2 antigen by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin embedded normal and neoplastic breast tissue using the ultraView Universal DAB Detection Kit on a BenchMark ULTRA instrument. This IHC device is indicated for identifying breast cancer patients who are eligible for treatment with Herceptin® (IHC 3+ or IHC 2+/ISH amplified), KADCYLA® (IHC 3+ or IHC 2+/ISH amplified) or ENHERTU® (IHC 1+ or IHC 2+/ISH non-amplified). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for in vitro diagnostic

(IVD) use.

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CAUSES FOR REJECTION

Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than 10% neutral buffered formalin. Paraffin blocks that have been overheated or frozen. Unlabeled/mislabeled specimens.

COLLECTION AND TRANSPORT

COLLECTION

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REFERENCES

REFERENCES

HGH

ALIAS HGH

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

HHV8

ALIAS Human Herpes virus 8

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Human Herpes Virus (HHV) 8 is the likely etiological agent of Kaposi's sarcoma (KS), and is present in all cases.

HHV 8 encodes a latent nuclear antigen (LANA) that is the product of the viral gene of 73. HHV8 has also been

identified in multicentric Castleman disease (MCD), and primary effusion lymphoma (PEL).

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ **GL**, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

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- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

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COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

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REFERENCES

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needed.

H. PYLORI

ALIAS Helicobacter Pylori

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION This antibody reacts with *H. pylori* on the surface and in the cytoplasm of epithelial cells of stomach biopsies.

Studies have shown that *H. pylori* plays an important role in the etiology of chronic active gastritis and the development of panticular disease. Immunohistochemistry can provide rapid detection of this bacterium

development of peptic ulcer disease. Immunohistochemistry can provide rapid detection of this bacterium.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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HPV (IHC)

ALIAS Human Papillomavirus (HPV)

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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(Nat Rev Cancer 2010;10:550)

ALIAS HPV ISH LOW (6,11), HPV ISH HIGH (16,18), HPV ISH High Risk (31,33,51)

LABORATORY Pathology
CPT* 88364, 88365

TEST DESCRIPTION In situ hybridization on FFPE tissues for qualitative detection of E6/E7 mRNA in HPV subtypes with the

complete panel: low risk (6, 11) plus high risk (16, 18, 31, 33, 51). Testing with the complete panel is

recommended, but orders for partial panels are accepted. Reports will identify which component or cocktail is

positive but will not identify specific subtypes as positive.

METHODOLOGY In Situ Hybridization (ISH)

TURNAROUND TIME 5 days

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ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Antibody clone HMB45 recognizes a melanoma-specific antigen by reacting with melanoma cells, nevus cells

and neonatal melanocytes. HMB45 is expressed on the majority of malignant melanoma cases as well as on

tumors of melanocytic differentiation.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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HNF-1 BETA IHC STAINS

ALIAS Hepatocyte nuclear factor-1 Beta

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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HSV I/II

ALIAS Herpes Simplex 1 Antigen, Herpes Simplex 2 Antigen

LABORATORY Pathology
CPT* 88341, 88342

This antibody cocktail reacts with Herpes Simplex Virus (HSV) type 1- or type 2-specific antigens and with

antigens common to both types. The antibodies react with all the major glycoproteins present in the viral envelope and at least one core protein as determined by crossed immunoelectrophoresis. Neither antibody cross-reacts with cytomegalovirus or Epstein-Barr virus. The cocktail is well suited for the detection of HSV in human cellular material obtained from superficial lesions or biopsies and for the early identification of HSV in

infected tissue cultures.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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hTERT IHCSTAINS

ALIAS Human Telomerase Reverse Transcriptase (hTERT)

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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INHIBIN A IHCSTAINS

ALIAS Inhibin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTIONAnti-Inhibin alpha is an antibody against a peptide hormone which has a demonstrated utility in differentiating

between adrenocortical tumors and renal cell carcinoma. This antibody stains most adrenal tumors but no cases of renal cell carcinomas (RCC). Sex cord stromal tumors of the ovary, as well as trophoblastic tumors, also

demonstrate cytoplasmic positivity with this antibody.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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KAPPA

ALIAS Kappa Light Chain by IHC

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Antibody to the kappa light chain of immunoglobulin is reportedly useful in the identification of leukemias,

plasmacytomas and certain non-Hodgkin lymphomas. Demonstration of monotypism in lymphoid infiltrates is a

surrogate for clonality, and therefore malignancy.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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KDX1

ALIAS KDX1

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

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Ki67

 ALIAS
 Ki67 (MIB-1)

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Ki67 is a nuclear protein that is expressed in proliferating cells. Ki67 is preferentially expressed during late G1,

S, M, and G2 phases of the cell cycle, while cells in the G0 (quiescent) phase are negative for this protein. Increased proliferative activity is associated with more aggressive tumor and decreased disease-free survival

period.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

LAMBDA

ALIAS Lambda Light Chain IgG

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Antibody to the lambda light chain of immunoglobulin is reportedly useful in the identification of leukemias,

plasmacytomas and certain non-Hodgkin lymphomas. Demonstration of monotypism in lymphoid infiltrates is a

surrogate for clonality, and therefore malignancy.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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LEVELS OF SERVICE ✓ **GL**, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

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CAUSES FOR REJECTION

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REFERENCES

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MAMMAGLOBIN

ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Mammaglobin is a breast-associated glycoprotein. In normal breast tissue, this antibody labels breast ductal

and lobular epithelial cells. In tumor cells, they are reactive with all types of breast adenocarcinoma regardless

of tumor differentiation and type. Adenocarcinomas from other organs rarely express mammaglobin.

Mammaglobin can help in the identification of primary sites of carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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MELAN-A IHC STAINS

ALIAS Melanoma Antigen Recognized by T-cells 1

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Melan A (Mart1, Melanoma Antigen Recognized by T-cells 1), is a differentiation antigen that is expressed in

melanocytes, most melanomas. Melan A recognizes a subcellular fraction found in melanosomes. Melan A is a useful addition to melanoma panels since it is specific for melanocytic lesions. Both HMB 45 and Melan A are co-expressed in the majority of melanomas, as well as uniquely expressed in certain cases. Melan A antibody, A103 clone labels the tumor cells of a subset of adrenocortical carcinomas and sex cord tumors of the gonads.

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MITF

ALIAS Microphthalmia transcription factor

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION MITF (microphthalmia transcription factor) is a transcription factor that regulates the development and survival

of melanocytes. MITF is restricted to the melanocyte cell lineage. Anti-MITF recognizes a nuclear protein that is expressed in the majority of primary and metastatic epithelioid malignant melanomas as well as in normal

melanocytes, benign nevi and dysplastic nevi.

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MLH1 IHC STAINS

ALIAS MLH1
LABORATORY Pathology

CPT* 88341, 88342, 88360, 88361

TEST DESCRIPTION MLH1, a mismatch repair protein involved in maintaining the integrity of genetic information, alongside MSH2,

MSH6 and PMS2. During DNA replication, strand misalignment can occur resulting in alterations to microsatellite repeats, often referred to as microsatellite instability (MSI). These defects in DNA repair pathways have been linked to human carcinogenesis. Mutations in the *MLH1* gene have been reported to be found in tumors with MSI, such as some forms of colon cancer eg. Hereditary nonpolyposis colon cancer (HNPCC), a subset of sporadic carcinomas and breast cancer. Loss of expression of MLH1 has also been reported in acute lymphoblastic leukemia, endometrial carcinoma, gastric carcinoma and ovarian carcinoma.

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MSH2 IHC STAINS

ALIAS Human mismatch repair protein 2

LABORATORY Pathology

CPT* 88341, 88342, 88360, 88361

TEST DESCRIPTION Human mismatch repair protein 2 (MSH2) is involved in the initial recognition of mismatched nucleotides

during the post replication mismatch repair process. Loss of MSH2 function leads to the accumulation of replication errors, which in turn may be responsible for the multiple mutations required for multistage carcinogenesis. Mutations in *MSH2* gene is linked to hereditary nonpolyposis colon cancer and to sporadic

cancers which exhibit microsatellite instability.

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REFERENCES

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MSH6

ALIAS MSH6
LABORATORY Pathology

CPT* 88341, 88342, 88360, 88361

TEST DESCRIPTION Mismatch repair (MMR) genes results in failure to repair errors in repetitive sequences that occur during DNA

replication. The defects in DNA repair pathways have been related to tumor carcinogenesis. MSH6 mutations appear to be associated with atypical HNPCC and in particular with development of endometrial carcinoma or atypical endometrial hyperplasia, the presumed precursor of endometrial cancer. Defects in MSH6 are also

found in familial colorectal cancers (suspected or incomplete HNPCC).

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REFERENCES

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MUC 2

 ALIAS
 Mucin 2

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Mucin 2 (MUC2) expression is detected in human tissues such as normal colon, breast, prostate, and salivary

gland, as well as in gastrointestinal, colonic, breast and prostate neoplasia. This antibody labels MUC2 in normal colon and colonic carcinomas where it produces intense perinuclear staining in goblet cells.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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MUM1

 ALIAS
 MUM1

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION The MUM1 antibody is specific for the MUM1/IRF4 protein that is overexpressed in late plasma-cell-directed

stages of B-cell differentiation. MUM1 is a powerful tool for understanding the histogenesis of B-cell lymphomas. MUM1 protein is an excellent marker for Hodgkin and Reed-Sternberg cells of classical Hodgkin lymphoma in combination with CD30. Furthermore, MUM1 seems to be a marker of prognostic value since it has been found that the expression of MUM1 is associated with the poor prognosis of patients with diffuse

large B-cell lymphoma (DLBCL).

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ALIAS Lysozyme

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Lysozyme is synthesized predominantly in reactive histiocytes rather than in resting, unstimulated phagocytes.

This antibody labels myeloid cells, histiocytes, granulocytes, macrophages and monocytes. It is helpful in the

identification of myeloid or monocytic nature of acute leukemia.

METHODOLOGY Immunohistochemistry (IHC)

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ALIAS Muscle Specific Actin (MSA)

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Muscle Specific Actin (MSA) antibody recognizes the alpha and gamma isotypes of skeletal, cardiac, and smooth

muscle cells. It is non-reactive with other mesenchymal cells and all epithelial cells except for myoepithelium. This antibody is useful in the identification of tumors with muscle differentiation and detection of myoepithelial

cells.

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REFERENCES

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 ALIAS
 MPO

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Myeloperoxidase (MPO) is an important enzyme used by granulocytes during phagocytic lysis of engulfed

foreign particles. In normal tissues and in a variety of myeloproliferative disorders, myeloid cells of both neutrophilic and eosinophilic types, at all stages of maturation, exhibit strong cytoplasmic reactivity for MPO.

MPO is useful in differentiating between myeloid and lymphoid leukemias.

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Attn: Accessioning Department

REFERENCES

REFERENCES

MyoD1 IHC STAINS

 ALIAS
 MyoD1

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION Nuclear expression of myogenic differentiation 1 (MyoD1) is restricted to skeletal muscle tissue and has been

demonstrated to be a sensitive marker of myogenic differentiation. The antibody strongly labels the nuclei of myoblasts in developing skeletal muscle tissue, whereas the majority of adult skeletal muscle is negative. MyoD1 immunostaining has been demonstrated in the majority of rhabdomyosarcomas of various histological

subtypes.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

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SPECIMEN REQUIREMENTS

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CAUSES FOR REJECTION

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REFERENCES

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MYOGENIN

ALIAS Myogenin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Expression of myogenin is restricted to cells of skeletal muscle origin. It is a useful marker for tumors of the

muscle lineage, being strongly expressed in alveolar rhabdomyosarcomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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MYOGLOBIN

ALIAS

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

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ALIAS SMMS-1
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Smooth Muscle Myosin, Heavy Chain (SMMS-1) is an antibody to smooth muscle myosin, heavy chain that

reacts with human visceral and vascular smooth muscle cells. The antibody also reacts with human myoepithelial cells. It is very helpful in distinguishing between benign sclerosing breast lesions and infiltrating carcinomas in difficult cases since it strongly stains the myoepithelial layer in the benign lesions while it is

negative in the infiltrating carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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NASPIN A IHC STAINS

ALIAS Naspin A
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Napsin A has a specific function in normal alveolar epithelium and is proposed to play a role in the proteolytic

processing of surfactant precursors. Napsin A is reported to be predominantly expressed in lamellar bodies of type II pneumocytes, secondary lysosomes of alveolar macrophages, respiratory epithelium of terminal and respiratory bronchioles, plasma cells, and within a subset of lymphocytes in normal lung as well as in epithelial cells of renal tubules in normal kidney. It is weakly expressed in normal spleen. Past studies have also reported that Napsin A is expressed in most primary lung adenocarcinomas. Napsin A expression may also be seen in

renal carcinoma.

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REFERENCES

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needed.

NKX3.1

ALIAS NKX3.1
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION NKX3.1 is a protein encoded by the NKX3.1 gene located on chromosome 8. NKX3.1 protein has been found to

be positive in the vast majority of primary prostatic adenocarcinomas. NKX3.1 stains nuclei in both normal and prostate cancer and along with other prostate-restricted markers, may be a valuable marker to definitively

determine prostatic origin in poorly differentiated metastatic carcinomas.

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REFERENCES

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NSE IHC STAINS

ALIAS Neuron Specific Enolase

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION In normal tissue, most neurons and their axonal and dendritic processes stain strongly positive for Neuron

Specific Enolase (NSE), with the exception of Purkinje cells. Schwann cells, cells of the adrenal medulla, and paraganglia also contain NSE. Endocrine cells of the skin (Merkel cells), respiratory and GI tract epithelium, pituitary parathyroid, and pancreatic islets and C cells of thyroid all stain positively for NSE. NSE is expressed in

ganglioneuromas, neuroblastomas, Schwannomas and malignant melanomas. It is also present in

pheochromocytomas and paragangliomas. Carcinoids, medullary thyroid carcinomas, pituitary adenomas and endocrine tumors of the pancreas and GI tract all show positive immunoreactivity for NSE. NSE is found in

neuroendocrine carcinoma of the skin (Merkel cell tumor) and small cell carcinoma of the lung.

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REFERENCES

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OCT (2)

ALIAS Octamer Binding Transcription Factor 2

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Octamer Binding Transcription Factor 2 (OCT2) is present in all B-cells expressing Ig. The combination of BOB1

and OCT2 stains is helpful in distinguishing between classical Hodgkin lymphoma (at least one marker negative) and nodular lymphocyte predominant Hodgkin lymphoma (both markers expressed). Classical Hodgkin lymphoma stains as BOB1-OCT2+ or BOB1+ OCT2-, while nodular lymphocyte predominant Hodgkin lymphoma

(NLPHL) or diffuse large B-cell lymphoma (DLBCL) stains BOB1+ OCT2+.

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OCT (3/4)

ALIAS Octamer Binding Transcription Factor 3/4

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Octamer Binding Transcription Factor 4 (OCT4, also known as OCT3/4, POU51) is a transcription factor and is

expressed by early embryonic cells, germ cells, and stem cells. OCT4 is a nuclear marker of classical seminoma and embryonal carcinoma. It has excellent sensitivity and specificity for these two tumors, and can be used as

the "screen" for these neoplasms when dealing with a metastatic tumor of unknown origin.

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P16

 ALIAS
 p16

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION p16 (p16 -INK4a, p16-MTS1, inhibitor of CDK4) is the product of the CDKN2 gene. It inhibits the progression of

the cell cycle through the G1 phase. p16 is a candidate tumor suppressor, whose gene is frequently deleted or mutated in tumors such as melanomas, gliomas, esophageal, pancreatic, lung, and urinary bladder carcinomas, and some types of leukemias. p16 expression is associated with high-risk human papillomavirus in cervical

cancer and head and neck tumors.

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REFERENCES

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P40

 ALIAS
 p40

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION p40 antibody recognizes ΔNp63—a p63 isoform. It is equivalent to p63 in sensitivity for squamous cell

carcinoma, but it is markedly superior to p63 in specificity, which eliminates a potential pitfall of

misinterpreting a p63-positive adenocarcinoma as squamous cell carcinoma. These findings strongly support

the routine use of p40 for the diagnosis of pulmonary squamous cell carcinoma.

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REFERENCES

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P504S (AMACR)

ALIAS Alpha-methylacyl-CoA Racemase (AMACR)

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Expression of P504S protein, or Alpha-methylacyl-CoA Racemase (AMACR), is found in prostatic

adenocarcinoma but not in benign prostatic tissue. It has also been found to stain premalignant lesions of the prostate, high-grade prostatic intraepithelial neoplasia (PIN) and atypical adenomatous hyperplasia. P504S stains the vast majority of prostate cancers, and P504S has been shown to stain numerous other tumor types, such as hepatoma, breast carcinoma, pancreatic islet tumor and desmoplastic small round cell tumor.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

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Specimen Labeling

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STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
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Attn: Accessioning Department

REFERENCES

REFERENCES

P53 IHC STAINS

ALIAS P53
LABORATORY Pathology

CPT* 88341, 88342, 88360, 88361

TEST DESCRIPTION The product of the p53 gene is a nuclear phosphoprotein that regulates cell proliferation. Excess accumulation

of the mutant p53 gene product results in inactivation of its tumor suppressor function and cellular

transformation. Overexpression of mutant p53 gene has also been associated with high proliferative rates and

poor prognosis in breast, colon, lung, and brain cancer, as well as in some leukemias and lymphomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

REFERENCES

P63 IHC STAINS

 ALIAS
 P63

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION p63 is a homologue of the p53 gene and is necessary for normal breast and prostate development. Unlike other

markers of myoepithelial cells and basal cells, p63 immunoreactivity is localized to the nucleus of the cells, which can offer distinct advantages over cytoplasmic labeling in certain types of cases. p63, as a marker of myoepithelial and basal cells, is extremely useful in diagnostic surgical pathology, particularly when examining difficult breast biopsies and prostate biopsies. p63 is also a marker of squamous cell and erothelial carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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P120 CATENIN IHC STAINS

ALIAS P120 Catenin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION P120 Catenin is a tyrosine kinase which binds to E-cadherin within the cell membrane. It is detectable in the cell

membranes of a wide variety of cells but predominates in virtually all types of epithelia. When E-cadherin is absent, P120ctn moves to the cell cytoplasm. P120ctn can be useful in the diagnostic distinction between

lobular (cytoplasmic staining pattern) and ductal (membranous) breast neoplasia.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

ALIAS Periodic Acid Schiff (PAS) with digestion (PAS-D) for fungus

LABORATORY Pathology
CPT* 88312
TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

REFERENCES

PAX2 IHC STAINS

ALIAS Paired Box 2
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Paired Box 2 (PAX2) is a transcription factor that is essential for kidney development. In kidneys of normal

adult, Pax2 protein expression is limited to nuclei of collecting ducts and to a lesser extent in distal tubules. PAX2 is expressed in early kidney organogenesis as well as in Wilms' tumor and renal cell carcinoma. PAX2 can

be useful in the diagnosis of renal cell carcinoma.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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PAX5 IHC STAINS

ALIAS Paired Box 5
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Paired Box 5 (PAX5) is a B-cell specific activator protein (BSAP). In early stages of B-cell development, PAX5

influences the expression of several B-cell specific genes, such as CD19 and CD20. PAX5 is expressed primarily in pro-, pre-, and mature B-cells, but not in plasma cells. There is an excellent correlation between CD20 and PAX5 expression; however, anti-PAX5 exceeds the specificity and sensitivity of L26 (CD20) because of its earlier expression in B-cell differentiation and its ability to detect all committed B-cells, including classic Hodgkin

lymphoma. It is very specific to B-cell lineage and does not stain T-cells.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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SPECIMEN REQUIREMENTS

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REFERENCES

REFERENCES

PAX8 IHC STAINS

ALIAS Paired Box 8

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION The *PAX8* gene is a member of the paired box (PAX) family of transcription factors. This family plays critical

roles during fetal development and cancer growth. PAX8 is involved in kidney cell differentiation, and thyroid development. PAX8 has been shown to be expressed in three of the most common types of renal cell carcinoma including clear cell, chromophobe and papillary carcinoma. PAX8 stains nuclei exclusively and performs well in formalin-fixed paraffin-embedded (FFPE) tissues. PAX8 has been shown to be positive in

thyroid and ovarian carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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LEVELS OF SERVICE

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SPECIMEN REQUIREMENTS

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COLLECTION AND TRANSPORT

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REFERENCES

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ALIAS PCK (AE1/AE3) (Multicytkeratin-MCK)

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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PDL1 (22C3)

 ALIAS
 PD-L1 (22C3)

 LABORATORY
 Pathology

 CPT*
 88360

TEST DESCRIPTION PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1,

Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-

small cell lung cancer (NSCLC) tissue.

METHODOLOGY Immunohistochemistry (IHC)

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LEVELS OF SERVICE ✓ **GL**, Technical Component and Professional Service or

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SPECIMEN REQUIREMENTS

SPECIMEN TYPE

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

VOLUME

SPECIAL INSTRUCTIONS

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- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
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CAUSES FOR REJECTION

Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than 10% neutral buffered formalin. Paraffin blocks that have been overheated or frozen. Unlabeled/mislabeled specimens.

COLLECTION AND TRANSPORT

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REFERENCES

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ALIAS PIN 4 (Prostate Triple Stain)

LABORATORY Pathology
CPT* 88344

TEST DESCRIPTION

The combination of p63 + CK HMW + P504S (PIN-4 cocktail) can be extremely useful for diagnosing prostatic

intraepithelial neoplasia (PIN) and/or prostate carcinoma, especially in difficult cases with limited tissue. P504 stains (cytoplasm red) prostate adenocarcinoma and atypical adenomatous hyperplasia. p63 (nuclear brown) and cytokeratin high molecular weight (HMW, cytoplasmic brown) stain basal cells of all normal (negative

markers) and benign prostate glands.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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PLAPIHC STAINS

ALIAS Placental Alkaline Phosphatase

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Normally human Placental Alkaline Phosphatase (PLAP) is produced by syncytiotrophoblasts after the twelfth

week of pregnancy. PLAP is expressed by both malignant somatic and germ cell tumors. PLAP can be useful in

distinguishing seminoma and embryonal carcinomas from undifferentiated malignant tumors.

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 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

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PMS2

ALIAS PMS2 LABORATORY Pathology

CPT* 88341, 88342, 88360, 88361

TEST DESCRIPTION PMS2, also known as PMS1 protein homologue 2, is a DNA mismatch repair (MMR) protein. The PMS2 protein

forms a heterodimer with the MLH1 protein which is then activated in the presence of ATP; this complex coordinates the binding of other proteins that repair DNA errors arising during cell preparation for cell division.

The loss of PMS2 expression in tumors can be helpful in identifying hMLH1 mutation carriers. *PMS2* gene defects account for a small but significant proportion of colorectal cancers and for a substantial proportion of

tumors with microsatellite instability.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

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CAUSES FOR REJECTION

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PR IHC STAINS

ALIAS Progesterone Receptor

LABORATORY Pathology

CPT* 88341, 88342, 88360

TEST DESCRIPTION Progesterone Receptor (PR) belongs to a superfamily of nuclear hormone receptors. Estrogen Receptor (ER)

induces PR expression, therefore, PR status serves as an indicator of an intact ER pathway. There are two known isoforms of PR; PR α and PR β . The current assays in clinical breast cancer measure both isoforms. PR is expressed in about 60-70% of invasive breast cancers. It is a weak prognostic factor by itself but a modest predictive factor that adds to the predictive value of ER for response to endocrine therapies, both in adjuvant and metastatic settings. The primary indication to assess PR in breast cancer is to predict response to hormonal therapies, such as tamoxifen, other selective estrogen receptor modulators (SERMs) and aromatase inhibitors.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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PROLACTIN

ALIAS Prolactin

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Prolactin is a growth factor secreted by the anterior pituitary that is necessary for the proliferation and

differentiation of the mammary glands. Prolactin antibody is useful in the identification of prolactin in pituitary

adenomas.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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PROSTEIN

ALIAS P501S
LABORATORY Pathology
CPT* 88342

TEST DESCRIPTION P501S protein, also called the prostein, is a type IIIa plasma membrane protein which is exclusively

expressed in cells of normal and malignant prostate. P501S expression has not been detected in other

normal or malignant glandular tissues.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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PSA IHC STAINS

ALIAS Prostatic Specific Antigen

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Need info

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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PSAP IHC STAINS

ALIAS Prostate Specific Alkaline Antigen Phosphatase

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Prostate specific acid phosphatase/human prostatic acid phosphatse (PSAP/HPAP) is a 100kDa glycoprotein

present in high concentration in the prostate gland and its secretions. PSAP is specific to the benign or malignant epithelial cells of the prostate gland. Prostatic stroma, urethra and the basal cells stain negatively. Also, epithelial cells injured due to inflammation, infarction, etc. and areas of squamous metaplasia of the prostatic acini show loss of PSAP activity. Nearly all metastases of prostatic carcinoma, irrespective of site,

demonstrate PSAP immunoreactivity.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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PTEN IHC STAINS

ALIAS PTEN
LABORATORY Pathology
CPT* 88374, 88377

TEST DESCRIPTION Phosphatase and tensin homolog (PTEN) is a tumor suppressor gene that is mutated in a wide range of cancers.

PTEN plays a role in cell proliferation, apoptosis and migration. Reduced expression of PTEN has been reported in a variety of malignancies, including breast, prostate and endometrial cancer, and may be observed in Cowden syndrome tumors. In breast and prostate cancer, loss of PTEN expression has been shown to correlate positively with advanced stage disease. Recent studies have reported that PTEN may be a powerful predictor of

response to Herceptin in HER2 positive breast cancer.

METHODOLOGY FISH
TURNAROUND TIME 3-5 c

3-5 days

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REFERENCES

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PTH IHC STAINS

ALIAS Parathyroid hormone

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Parathyroid hormone (PTH) is expressed in normal parathyroid, parathyroid adenomas and primary and

secondary hyperplasia of parathyroid. This antibody is useful in the differential diagnosis of autoimmune disorders involving parathyroid gland resulting in the production of anti-PTH & hypo-parathyroidism.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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ALIAS RCC
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION In normal kidney, renal cell carcinoma (RCC1, gp200) is localized along the brush border of the proximal tubule.

In other normal tissues, RCC is also localized along the luminal surfaces of breast lobules and ducts, the luminal surface of the epididymal tubular epithelium, within the cytoplasm of parathyroid parenchymal cells and focally within the colloid of thyroid follicles. Other normal tissues do not express similar or cross-reacting

antigens. RCC1 is expressed by most primary and metastatic renal cell carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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RETICULIN

ALIAS Reticulin

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

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REFERENCES

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S100

 ALIAS
 \$100

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION S100 belongs to the family of calcium binding proteins. Antibody to S100 stains Schwannomas, ependymomas,

astrogliomas, almost all benign melanocytic lesions, melanomas and their metastases. S100 protein is also expressed in the Langerhans cells in skin and interdigitating reticulum cells in the paracortex of lymph nodes.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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SALL4 IHC STAINS

ALIAS

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION SALL4, a newly identified zinc-finger transcriptional factor, is required for the maintenance of embryonic stem

cell pluripotency by modulating OCT4. SALL4 is a novel sensitive and highly specific marker for metastatic germ

cell tumors, and is particularly useful for detecting metastatic yolk sac tumors.

METHODOLOGY Immunohistochemistry (IHC)

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Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

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STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

SEROTONIN

ALIAS

LABORATORYPathologyCPT*88341, 88342TEST DESCRIPTIONNEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

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REFERENCES

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SMA IHC STAINS

ALIAS Smooth Muscle Actin

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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SMMHC

ALIAS Smooth Muscle Myosin

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Smooth Muscle Myosin, Heavy Chain (SMMS-1) is an antibody to smooth muscle myosin, heavy chain that

reacts with human visceral and vascular smooth muscle cells. The antibody also reacts with human myoepithelial cells. It is very helpful in distinguishing between benign sclerosing breast lesions and infiltrating carcinomas in difficult cases since it strongly stains the myoepithelial layer in the benign lesions while it is

negative in the infiltrating carcinomas.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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SOX10

ALIAS SOX10
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION SOX10 is a sensitive marker of melanoma, including conventional, spindled, and desmoplastic subtypes. It is

also a useful marker in detecting both the in situ and invasive components of desmoplastic melanoma. SOX10 is diffusely expressed in schwannoma, neurofibroma, and granular cell tumor. SOX10 was not identified in any

other mesenchymal and epithelial tumors except for myoepitheliomas and diffuse astrocytomas.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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SYNAPTOPHYSIN

ALIAS Synaptophysin LABORATORY Pathology CPT* 88341, 88342

TEST DESCRIPTION Antibody to synaptophysin reacts with neuroendocrine neoplasms of neural as well as epithelial types. In

combination with chromogranin A and NSE antibodies, the antibody to synaptophysin is very useful in the

identification of normal neuroendocrine cells and neuroendocrine neoplasms.

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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ALIAS TdT

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTIONTdT is a highly specific marker for the diagnosis and classification of acute lymphoblastic lymphoma/leukemias.

The determination of TdT expression is most valuable when it is important to differentiate histologically

between lymphoblastic lymphoma and Burkitt lymphoma.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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REFERENCES

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ALIAS Spirochete
LABORATORY Pathology
CPT* 88342

TEST DESCRIPTION Spirochete (*Treponema pallidum*) is the causative agent of syphilis. In the past, localization of the spirochete

agent was achieved with silver stains such as Steiners and/or Warthin-Starry. Treponema pallidum can now be successfully localized with IHC techniques in FFPE tissue. The antibody consists of a rabbit purified IgG fraction and is highly specific for spirochete. Treponema palladium also cross-reacts with *Borrelia burgdorferi* (Lyme

disease).

METHODOLOGY Immunohistochemistry (IHC)

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REFERENCES

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TTF-1

ALIAS Thyroid Transcription Factory

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Thyroid Transcription Factory (TTF1) is found is found predominantly in lung and thyroid neoplasms. The utility

of TTF1 becomes apparent in the differential diagnosis of primary versus metastatic carcinomas, especially in

the lung. This clone is sensitive and may show weak staining in non-lung tissues.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

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ALIAS TM

LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Thrombomodulin (TM) is a plasma membrane-related glycoprotein that has anticoagulant activity. TM antigen

is found in several cell types, including megakaryocytes, mesangial cells, synovial cells, mesothelial cells, endothelial cells, and some squamous epithelial cells and their associated tumors. TM antibody labels most mesotheliomas with thick membranous staining pattern and about half of pulmonary adenocarcinomas, showing cytoplasmic immunostaining. Thrombomodulin is also a marker of urinary bladder epithelium.

METHODOLOGY Immunohistochemistry (IHC)

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THYROGLOBULIN

 ALIAS
 TGB

 LABORATORY
 Pathology

 CPT*
 88341, 88342

TEST DESCRIPTION This antibody labels thyroglobulin (TGB) in follicular epithelial cells of the thyroid and colloid. Thyroglobulin

antibody is useful in positive identification of thyroid carcinomas of the papillary and follicular types.

Demonstration of thyroglobulin in a metastatic lesion establishes the thyroid origin of the tumor.

METHODOLOGY Immunohistochemistry (IHC)

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ALIAS Thrichrome (Blue or Green)

LABORATORY Pathology
CPT* 88313

TEST DESCRIPTION Trichrome Staining (Blue or Green) is intended for laboratory use as a qualitative histologic stain to

demonstrate collagen fibers, muscle and connective tissue by light microscopy in sections of formalin-fixed, paraffin-embedded (FFPE) tissue stained on a BenchMark Special Stains instrument. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical

information, and proper controls. This product is intended for in vitro diagnostic (IVD) use

METHODOLOGY Immunohistochemistry (IHC)

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TYROSINASE IHC STAINS

ALIAS Tyrosinase

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTIONTyrosinase is a copper-containing metalloglycoprotein that catalyzes several steps in the melanin pigment

biosynthetic pathway. Mutations of the tyrosinase gene occur in various forms of albinism. Tyrosinase is one of the targets for cytotoxic T-cell recognition in melanoma patients. Staining of melanomas with this antibody

showed tyrosinase in melanotic as well as amelanotic variants.

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- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
 Standard pickup hours are 7am to 7pm ET (Monday to Friday)

Please contact us with any questions, shipping label inquiries, and any special arrangements needed.

 Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

TRYPTASE

ALIAS Tryptase (Mast Cell Tryptase - MCT)

LABORATORY Pathology
CPT* 88342

TEST DESCRIPTION This antibody labels a mast cell tryptase. It will also show reactivity to basophils, but to a lesser degree.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

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Attn: Accessioning Department

REFERENCES

REFERENCES

UROPLAKIN II

ALIAS Uroplakin II

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Uroplakin II is a 15 kDa protein component of urothelial plaques. Uroplakin II mRNA was found in both bladder

cancer tissues and peripheral blood of patients with primary and metastatic urothelial carcinoma of the bladder. Uroplakin II antibody [BC21] is a highly specific antibody that may be useful in identifying tumors of

urothelial origin.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

ALIAS Villin
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION This antibody recognizes villin, a cytoskeletal filament protein of 58 kDa found in human renal epithelial cells.

Villin antibody is useful for the study of gastrointestinal cells in normal and tumor tissues.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Block or Slides. Store at 2-8° C. Do not freeze. The user must validate any storage conditions other than those specified in the package insert. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

VIMENTIN

ALIAS Vimentin

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION Vimentin is the major intermediate filament in a variety of mesenchymal cells, including endothelial cells, all

fibroblastic cells, macrophages, Sertoli cells, melanocytes, lymphocytes and ovarian granulosa cells. Vimentin is

found in all types of sarcomas and lymphomas. Positive staining for vimentin is seen in most cells of fibrosarcomas, liposarcomas, malignant fibrous histocytomas, angiosarcomas, chondrosarcomas and

lymphomas. All melanomas and Schwannomas are strongly vimentin-positive.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

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If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ALIAS VWF
LABORATORY Pathology
CPT* 88341, 88342
TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

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COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

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If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

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STORAGE AND TRANSPORT

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REFERENCES

REFERENCES

WTF1

ALIAS Wilms Tumor
LABORATORY Pathology
CPT* 88341, 88342

TEST DESCRIPTION Wilms tumor susceptibility gene 1 protein (WT1) has diagnostic utility in the distinction of mesothelioma from

adenocarcinoma in tissue sections of pleural tumors. WT1 diffusely stains most ovarian serous carcinomas and

all Wilms tumors.

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

ZAP70

ALIAS Zeta-associated protein-70

LABORATORY Pathology

CPT* 88341, 88342

TEST DESCRIPTION NEED INFO

METHODOLOGY Immunohistochemistry (IHC)

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Formalin-fixed, paraffin-embedded tissue (FFPE), cut at 4-5 microns on a positively charged slide.

COLLECTION CONTAINER 10% neutral buffered formalin

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE CAUSES FOR REJECTION

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

Unlabeled/mislabeled specimens. A slide where no charge was used. Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than what is recommended by the manufacturer. Sections were distorted.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

Step 1. Tissue removed during a surgical procedure and placed in 10% NBF soon after removal from the patient. Appropriate tissue for requested staining.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

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STORAGE AND TRANSPORT

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SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

HPV ISH DNA

ALIAS Human papillomavirus

LABORATORY Pathology
CPT* 88366

TEST DESCRIPTION HPV DNA Tissue Testing is performed on FFPE tissue. It uses PCR and fragment analysis for qualitative detection

and genotyping of human papillomavirus (HPV) low risk types 6/11 and high-risk types 16, 18, 31, 33, 45, and 58. HPV DNA testing on FFPE tissue in head and neck squamous cell carcinomas (HNSCC), anogenital, and cervical lesions provides a complementary or alternative method to testing by p16 IHC or HPV ISH. In anogenital specimens, testing can distinguish presence of low-risk HPV types 6 and 11, associated with benign warts, from high-risk types which are associated with approximately 90% of anal cancers, 40% of vaginal cancers, and 40% of penile cancers. HPV is detected in up to 60-70% of oropharyngeal cancers and approximately 30% of HNSCC overall. HPV status serves as a prognostic marker head and neck cancer.

METHODOLOGY Molecular

TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Any FFPE tissue.

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

VOLUME • FFPE tissue block

· One H&E slide, with a clearly marked area of interest

Pathology Report, including IHC score*

OPTION 2: SUBMIT SLIDES

Five unstained 4-micron positively charged slides (minimum of two slides needed)
 Note: If slides are being submitted for testing, please document on the requisition the date of when slides were cut. Ideally, sections should not be used for HER2 testing if cut >6 weeks earlier. It is at the Medical Director's discretion to report out such results.

One H&E slide, with a clearly marked area of interest

Pathology Report, including IHC score*

SPECIAL INSTRUCTIONS

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Slides or paraffin blocks with no tissue remaining. Samples fixed in fixatives other than 10% neutral buffered formalin. Paraffin blocks that have been overheated or frozen. Unlabeled/mislabeled specimens.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. At the physician's office, use active communication to ensure the identity of the patient is correct (must use two identifiers, e.g. name, date of birth). Ensure a label with the two identifiers is affixed to the primary specimen container.

Step 2. Perform specimen collection following surgical protocol.

Step 3. Ensure the collection container cap is tightly sealed to prevent leakage.

Step 4. Document collection date, time, and fixation information.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the IHC Stain & Scan Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ALIAS Covid-19 (Nasal) by PCR LABORATORY Molecular Infectious

CPT* 87635

TEST DESCRIPTION Reverse transcription-polymerase chain reaction procedure used to convert viral RNA in a sample, if present,

into complementary DNA (cDNA), which is subsequently amplified using primers specific to three genes in the SARs-CoV-2 genome. If these same genes are present on the patient-derived cDNA, the primers will anneal and initiate copying of this sequence with polymerase. Detection of multiple genes in a single run (multiplex PCR) provides coverage of possible variants. The reaction is repeated for several cycles, with the amount of target sequence doubling after each cycle. Amplification of the target sequences are detected in real time by

fluorescence and are seen as exponential curves when graphed.

METHODOLOGY Molecular PCR
TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Nasal Swab

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

VOLUME 1mL

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION Unlabeled/mislabeled specimens. Specimen leal

Unlabeled/mislabeled specimens. Specimen leak during transit. Insufficient specimen quantity. No swab present in container. Refrigerated samples greater than 72 hours old. Room temperature samples greater than 24 hours old.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. Insert swab into one nostril until tip reaches posterior nasopharynx (halfway between nostrils and outer opening of ear)

Step 2. Rotate swab over surface of posterior nasopharynx

Step 3. Withdraw swab from collection site

Step 4. Repeat procedure for the second nostril with same swab

Step 5. Insert swab into transport tube and seal tube

Step 6. Immediately transport specimen to the laboratory

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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Attn: Accessioning Department

REFERENCES

REFERENCES

ALIAS Covid-19 (Saliva) by PCR LABORATORY Molecular Infectious

CPT* 87635

TEST DESCRIPTION Reverse transcription-polymerase chain reaction procedure used to convert viral RNA in a sample, if present,

into complementary DNA (cDNA), which is subsequently amplified using a primer specific to the N gene of SARS-CoV-2. If the N gene is present in the patient-derived cDNA, the primers will anneal and initiate copying of this sequence with polymerase. The reaction is repeated for several cycles, with the amount of target sequence doubling after each cycle. Amplification of the target sequence is detected in real time by

fluorescence and is seen as an exponential curve when graphed.

METHODOLOGY Molecular PCR
TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Saliva

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

VOLUME 1 ml. – 1.5 ml. saliva

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. Specimen leak during transit. Too much saliva (need 1.0 - 1.5 mL of liquid saliva, not including bubbles, but no more). Too little saliva (below 1.0 mL). Discoloration. Visible clumps of food, mucus, or other residues like toothpaste. Room temperature samples greater than 7 days old.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

- Step 1. Open saliva collection tube, patient should begin pooling saliva in their mouth.
- Step 2. Saliva should be **clear, watery fluid** (no sputum, coughing, thick material, or food
- particles).
- Step 3. Fill the tube up to or just above the fill-line (at least 1 ml, excluding bubbles); tightly close cap.
- Step 4. Immediately transport specimen to the laboratory

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT SPECIMEN PICK-UP OR

SHIPPING

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

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Attn: Accessioning Department

REFERENCES

REFERENCES

ALIAS Covid-19, Influenza A, Influenza B (Nasal) by PCR

LABORATORY Molecular Infectious
CPT* 87635 and 87804

TEST DESCRIPTION Reverse transcription-polymerase chain reaction procedure used to convert viral RNA in a sample, if present,

into complementary DNA (cDNA), which is subsequently amplified using primers specific to genes found in SARs-COV-2, influenza A, and influenza B. If any of these viral genes are present in the patient cDNA, primers will anneal and initiate copying of the sequence with polymerase. This multiplex PCR setup allows for detection of 3 different viral pathogens in one reaction. The reaction is repeated for several cycles, with the amount of target sequence doubling after each cycle. Amplification of the target sequences are detected in real time by

fluorescence and are seen as exponential curves when graphed.

METHODOLOGY Molecular PCR
TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Nasal Swab

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

VOLUME 1mL

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION

Unlabeled/mislabeled specimens. Specimen leak during transit. Insufficient specimen quantity. No swab present in container. Refrigerated samples greater than 72 hours old. Room temperature samples greater than 24 hours old.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

- Step 1. Insert swab into one nostril until tip reaches posterior nasopharynx (halfway between nostrils and outer opening of ear)
- Step 2. Rotate swab over surface of posterior nasopharynx
- Step 3. Withdraw swab from collection site
- Step 4. Repeat procedure for the second nostril with same swab
- Step 5. Insert swab into transport tube and seal tube
 Step 6. Immediately transport specimen to the laboratory

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

Call 1-888-ACUPATH (228-7284) to schedule same day courier pickup.
 Standard pickup hours are 7am to 7pm ET (Monday to Friday)

Please contact us with any questions, shipping label inquiries, and any special arrangements needed Send via FedEx or UPS to: Acupath Laboratories, Inc. 28 S. Terminal Drive Plainview, NY 11803

Attn: Accessioning Department

REFERENCES

REFERENCES

ALIAS Gastrointestinal Pathogen (GI) Panel by PCR

 LABORATORY
 Molecular Infectious

 CPT*
 87505, 87506, 87507

TEST DESCRIPTION A multiplexed nucleic acid test for the detection of multiple bacteria, viruses, and parasites from stool samples

in Cary Blair transport medium. Extraction, nested multiplex PCR, and endpoint melting curve data are all performed within the BioFire® GI panel pouch, a closed-system disposable. Any present pathogens are

identified by their melting temperatures.

METHODOLOGY Molecular PCR TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Stool

COLLECTION CONTAINER Stool collected in a sterile, leak-proof container with Cary Blair stool culture transport medium.

VOLUME

SPECIAL INSTRUCTIONS Follow the Coloff® Stool Collection Instruction Packet that came in the Acupath Molecular GI Pathogen Kit.

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION Unlabeled/mislabeled specimen. Specimen leak during transit. Solid specimen. Refrigerated sample more than 4 days old.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

- Step 1. Follow Steps 1-7 from the $\mathsf{Coloff}^{\mathbb{B}}$ Stool Collection Instruction Sheet from the Packet that came in the Acupath Molecular GI Pathogen Kit to obtain the stool for collection.
- Step 2. Open the vial(s) carefully. Using the collection spoon attached to the cap, add enough specimen until the liquid reaches the **ARROW** on the label.
- Step 3. Tightly close cap, place specimen bottle in transport bag and **immediately transport specimen to laboratory.**
- Step 4. Complete Steps 7-10 of the Coloff® Stool Collection Instruction Sheet

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ALIAS Respiratory Syncytial Virus, Influenza A and Influenza B (Nasal) by PCR

LABORATORY Molecular Infectious
CPT* 87807 and 87804

TEST DESCRIPTION Real-time reverse transcription-polymerase chain reaction procedure for the detection of RSV, influenza A, and

influenza B. Bi-functional fluorescent probe-primers are used together with corresponding reverse primers for

specific genes found in RSV, flu A, and flu B.

METHODOLOGY Molecular PCR
TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ **GL**, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Nasal Swab

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

VOLUME 1mL
SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

• Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION Unlabeled/mislabeled specimens. Specimen leak during transit. Insufficient specimen quantity. No swab

present in container. Refrigerated samples greater than 72 hours old. Room temperature samples greater than 24 hours old.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. Insert swab into one nostril until tip reaches posterior nasopharynx (halfway between nostrils and outer opening of ear)

Step 2. Rotate swab over surface of posterior nasopharynx

Step 3. Withdraw swab from collection site

Step 4. Repeat procedure for the second nostril with same swab

Step 5. Insert swab into transport tube and seal tube

Step 6. Immediately transport specimen to the laboratory

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

SPECIMEN PICK-UP OR SHIPPING

Please contact us with any

questions, shipping label inquiries,

and any special arrangements

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

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REFERENCES

REFERENCES

needed

ALIAS Toenail Fungal Panel by PCR

LABORATORY Molecular Infectious

CPT* 87798, 87801 (x3), 87500, 87653, 87481, 87640, 87651, 87481, 88363

TEST DESCRIPTION Real-time PCR amplification is used to detect fungal microorganisms present in nail samples. The panel is

composed of both common and rarer fungal pathogens that are appropriate for clinical assessment and

treatment.

METHODOLOGY Molecular PCR TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Toenail

COLLECTION CONTAINER Collected in a sterile, leak-proof bag.

VOLUME Affected area as needed.

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION Unlabeled/mislabeled specimens. Specimen received in solution.

COLLECTION AND TRANSPORT

COLLECTION

Collection Procedure

- 1. Ensure the nail from which sample is to be collected is dry and devoid of any lotion or polish.
- Clip as much of nail as is comfortable and place into specimen bag.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

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UTI BY PCR INFECTIOUS MOLECULAR PCR

ALIAS Urinary Tract Infection by PCR

LABORATORY Molecular Infectious

CPT* 87798

TEST DESCRIPTION Real-time PCR amplification is used for the detection and differentiation of multiple pathogens, as well as their

antibiotic resistances, in urine samples. Advantages of PCR-based detection methods over traditional culture methods include swifter turnaround time, higher accuracy, and greater effectiveness in detecting co-infections.

METHODOLOGY Molecular PCR TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

√ TC, Technical Component only

Collected in a sterile, leak-proof container.

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Urine

COLLECTION CONTAINER

VOLUME

SPECIAL INSTRUCTIONS n/a

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

Electronic Order or completed Acupath Test Requisition form with prior relevant results.

• Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTION Unlabeled/mislabeled specimens

Unlabeled/mislabeled specimens. Specimen leak during transit. Insufficient specimen quantity. Samples received more than 5 days from date of collection.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

Step 1. Remove cap from sterile urine cup and avoid touching the interior.

Step 2. Wipe labia/head of penis with towelette.

Step 3. Begin urinating into toilet.

Step 4. While urinating, move the provided sterile cup into the stream of urine and fill halfway/

Step 5. Finish urinating into toilet.

Step 6. Submerge tip of provided transfer straw into cup of urine.

Step 7. With cap of tube in place and transfer straw submerge, push sample tube onto syringe of the transfer straw and pierce the rubber cap.

Step 8. Hold tube in place until flow stops.

Step 9. Remove tube and shake vigorously.

Step 10. Discard transfer straw into a sharps container.

Step 11. Transport only filled gray top tube to the lab.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

SPECIMEN PICK-UP OR SHIPPING

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REFERENCES

REFERENCES

ALIAS Wound Panel by PCR LABORATORY Molecular Infectious

CPT* 87075

TEST DESCRIPTION Real-time PCR amplification is used for the qualitative detection and differentiation of multiple pathogens, as

well as their antibiotic resistances, in wound swab specimens.

METHODOLOGY Molecular PCR
TURNAROUND TIME 24-48 hours

TAT is defined as the number of days from the date the specimen was received in the lab to the date the result is released to the ordering provider.

LEVELS OF SERVICE ✓ GL, Technical Component and Professional Service or

✓ TC, Technical Component only

SPECIMEN REQUIREMENTS

SPECIMEN TYPE Swab wound location(s)

COLLECTION CONTAINER Collected in a sterile, leak-proof container.

n/a

VOLUME 1 mL

THE FOLLOWING MUST BE INCLUDED WITH EACH SAMPLE

SPECIAL INSTRUCTIONS

- Electronic Order or completed Acupath Test Requisition form with prior relevant results.
- Billing information or payment (include copy of front and back of insurance card).

CAUSES FOR REJECTIONUnlabeled/mislabeled specimens. Specimen leak during transit. Insufficient specimen quantity. No swab present in container.

COLLECTION AND TRANSPORT

COLLECTION Collection Procedure

- Step 1. Clean the wound area, removing dead debris.
- Step 2. If the wound is dry, moisten swab with saline or sterile water.
- Step 3. Firmly sample the base or advancing margin of the lesion.
- Step 4. Insert swab into collection tube and break swab shaft the breakpoint. Replace cap.
- Step 5. Label and send specimen to lab.

Request Form or e-request

Test requests can be ordered electronically through our EMR system.

If not ordering electronically: complete and send the Acupath Molecular PCR Request Form with the specimen.

Specimen Labeling

Specimens must be Labeled with at least two unique identifiers (e.g., name, date of birth, or patient number), and where appropriate, specimen source.

STORAGE AND TRANSPORT

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

SPECIMEN PICK-UP OR SHIPPING

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